## July 18, 2022

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| 08:30-08:45 | **CASSS Welcome and Introductory Comments**  Carmilia Jiménez Ramírez, *BioMarin Pharmaceutical Inc.* |
| 08:45-09:00 | **CMC Strategy Forum Welcome and Introductory Comments**  Marc Verhagen, *Sanofi* |
| 09:00-10:45 | **Workshop I: Innovation and Science: Therapies of the Future**  Session Chairs: Nina Cauchon, *Amgen Inc.,* Zachary Kraus, *CDER, FDA*, Bernice Yeung, *Biogen*  Session Speakers:  **Process Development in the Age of Multispecifics and Novel Modalities**  Jennitte Stevens, *Amgen Inc.*  **Novel Modalities May Warrant Novel Product Quality Controls**  Deborah Schmiel, *CDER, FDA*  **Analytical Challenges and Solutions For an Orally Delivered Single-Domain Antibody (VHH/Nanobody)**  Bingchuan Wei, *Genentech, a Member of the Roche Group*  **Analytical Control Strategy for Antisense Oligonucleotide**  William Zhang, *Biogen* |
| 10:45-11:15 | **Networking Break** |
| 11:15-12:30 | **Workshop I: Panel Discussion - Q&A**  Panelists:  Deborah Schmiel, *CDER, FDA*  Marjorie Shapiro, *CDER, FDA*  Jennitte Stevens, *Amgen Inc.*  Bingchuan Wei, *Genentech, a Member of the Roche Group*  William Zhang, *Biogen* |
| 12:30-13:45 | **Networking Lunch** |
| 13:45-15:05 | **Workshop II: Analytical Evolution: Understanding Novel Modalities**  Session Chairs: Kogan Bao, *Molecular Templates*, Rebekah Ward, *Pfizer, Inc.*  Session Speakers:  **Characterization of Novel Biological Product Modalities: A Regulatory Perspective**  Leslie Rivera Rosado, *CDER, FDA*  **Characterization of mRNA Fragments to Evaluate Risk of Truncated or Off-Target Antigen Expression**  Thomas Lerch, *Pfizer, Inc*.  **Process Development Challenges for Bi-specific/Multi-specific Drug Development**  Twinkle Christian, *Amgen Inc.* |
| 15:05-15:30 | **Networking Break** |
| 15:30-16:45 | **Workshop II: Panel Discussion - Q&A**  Panelists:  Twinkle Christian, *Amgen Inc.*  Christopher Chumsae, *Bristol-Myers Squibb Company*  Dana Filoti, *AbbVie Inc.*  Flaviu Gruia, *Moderna, Inc.*  Tom Lerch, *Pfizer, Inc.*  Leslie Rivera Rosado, *CDER, FDA* |
| 16:45-18:00 | **Networking Reception** |
| 18:00 | **Adjourn Day One** |

## July 19, 2022

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| 09:00-10:20 | **Workshop III: Back to the Future: Leveraging Existing Playbooks to Create Robust Manufacturing Processes for Novel Modalities**  Session Chairs: Anna-Maria Hays Putnam, *Halozyme, Inc.,* Marc Verhagen, *Sanofi*  Session Speakers:  **Manufacturing Challenges for Bi-specific Antibodies from an FDA Standpoint**  Wen Jin Wu, *CDER, FDA*  **Leveraging a Novel Flexible Facility Concept to Provide Solutions to Current and Future Manufacturing Challenges**  Charles Christy, *Lonza*  **Development and Manufacturing of an Engineered IL-2, Reprogrammed for Anti-Tumor Therapy, Using a Semi-Synthetic Organism**  Christopher Means, *Synthorx, a Sanofi Company* |
| 10:20-10:50 | **Networking Break** |
| 10:50-12:10 | **Workshop III: Panel Discussion - Q&A**  Panelists:  Charles Christy, *Lonza*  Carolynn Grant*, Halozyme, Inc.*  Christopher Means, *Synthorx, a Sanofi Company*  Megan Powdrill, *Health Canada*  Wen Jin Wu, *CDER, FDA* |
| 12:10-13:25 | **Networking Lunch** |
| 13:25-15:10 | **Workshop IV: Connecting the Dots: Turning the Mechanism of Action of Novel Modalities Into a Suitable Potency Assay**  Session Chair: Eric Hales, *CDER, FDA*, Carmilia Jiménez Ramírez, *BioMarin Pharmaceutical Inc.*  Session Speakers:  **Expectations on Potency Assays for Antibody-based Novel Modalities – A Regulatory Perspective**  Nailing Zhang, *CDER. FDA*  **Cell-based Potency Assay: Design and Considerations**  Janani Kumar, *Molecular Templates*  **A Potent Solution to a Low Affinity Problem: Potency Release Methods for an NK Cell Targeted Cytokine**  Morgan Wilson*, InhibRx, Inc.*  **A High-Throughput Cell-Based Assay for Measuring mRNA-LNP Vaccine Product Potency**  Nicole Smiddy, *Merck & Co., Inc.* |
| 15:10-15:30 | **Networking Break** |
| 15:30-16:45 | **Workshop IV: Panel Discussion - Q&A**  Panelists:  Janani Kumar, *Molecular Templates*  Bhavin Parekh, *Eli Lilly and Company*  Catherine Shoemaker-Ramsey, *Biogen*  Nicole Smiddy, *Merck & Co., Inc.*  Morgan Wilson*, InhibRx, Inc.*  Nailing Zhang, *CDER, FDA* |
| 16:45-17:00 | **Closing Remarks and Invitation to CMC Strategy Forum January 2023**  Carmilia Jiménez Ramírez, *BioMarin Pharmaceutical Inc.* |
| 17:00 | **Adjournment** |