## 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** |