June 6, 2022

08:30-09:00	**CASSS Welcome & CGTP 2022 Introduction** Francis Poulin, *Laronde* Rob McCombie, *Syncopation Life Sciences*	
09:00-10:05	**Session I - Genome Editing** 09:05-09:25 Overview of Genome Editing Products and CMC Considerations Phillip Ramsey, *Sangamo Therapeutics* 09:25-09:45 Evaluating the Safety of Human Genome Editing with CRISPR/Cas9 Jonathan Phillips, *Intellia Therapeutics* 09:45-10:05 Defining and Understanding the Genome-Wide Off-Target Activity of CRISPR Genome Editors Cicera Lazzarotto, *St. Jude Children's Research Hospital*	**Panel Discussion** 10:05-10:35 Anna Kwilas, *CBER, FDA* Phillip Ramsey, *Sangamo Therapeutics* Jonathan Phillips, *Intellia Therapeutics* Cicera Lazzarotto, *St. Jude Children's Research Hospital*
10:35-11:20	**Networking Break**	
11:20-12:25	**Session II - Managing the Complexity of the CGTP Supply Chain** 11:20-11:45 Building a Cell Therapy Supply Chain: Leveraging Digital Solutions to Manage Complexity, Reduce Risks, and Setup for Commercialization Kawa Chiu, *Lyell Immunopharma* 11:45-12:05 Supply Chain Challenges of Fully Individualized Therapies James (Andy) Case, *Genentech, a Member of the Roche Group* 12:05-12:25 Capacity Planning Considerations for Autologous Cell Therapies Alicia Collins, *Bristol-Myers Squibb Company*	**Panel Discussion** 12:25-12:55 James (Andy) Case, *Genentech, a Member of the Roche Group* Kawa Chiu, *Lyell Immunopharma* Alicia Collins, *Bristol-Myers Squibb Company* Marcel Hoefnagel, *Medicines Evaluation Board, Netehrlands*
12:55-14:25	**Hosted Lunch**	
14:25-15:10	**Session III - Current Understanding of the Product Quality Attributes that Impact Safety and Efficacy of AAV-based Gene Therapy Products** 14:30-14:50 Potential Clinical Implications of AAV Gene Therapy Quality Attributes Sean Armour, *Spark Therapeutics, Inc.* 14:50-15:10 Gene Therapy for Neurological Diseases Junghae Suh, *Biogen*	**Panel Discussion** 15:10-16:00 Sean Armour, *Spark Therapeutics, Inc.* Claire Beuneu, *Federal Agency for Medicines and Health Products, Belgium* Leslie Nash, *Health Canada* Anurag Sharma, *CBER, FDA* Junghae Suh, *Biogen*
16:00-17:30	**Networking Reception**	

June 7, 2022

08:30-08:35	**Welcome Day 2** Michael Boyne, *COUR Pharmaceuticals Development Company, Inc.*	
08:35-09:40	**Session IV - Emerging Technologies** 08:40-09:00 Product Development and Manufacturing of oRNA Therapies Ben Maynor, *Orna Therapeutics* 09:00-09:20 Emerging mRNA Technology for Gene Therapy Qian Ruan, *Acrturus Therapeutics* 09:20-09:40 Reprogramming the Immune System Greta Wodarcyk, *COUR Pharmaceuticals Development Company, Inc.*	**Panel Discussion** 09:40-10:10 Ben Maynor, *Orna Therapeutics* Steven Oh, *CBER, FDA* Qian Ruan, *Acrturus Therapeutics* Greta Wodarcyk, *COUR Pharmaceuticals Development Company, Inc.*
10:10-10:55	**Networking Break**	
10:55-11:40	**Session V - Potency Assays** 11:00-11:20 Approach to AAV GTx Potency Strategy in the Context of a Comprehensive Control Strategy Savita Sankar, *Pfizer, Inc.* 11:20-11:40 Infectious Titer Assay Applications for Viral Vector Product Development & Control Simon Godwin, *Sanofi*	**Panel Discussion** 11:40-12:30 Simon Godwin, *Sanofi* Andrew Harmon, *CBER, FDA* Ivana Haunerová, *State Institute for Drug Control, Czech Republic* Savita Sankar, *Pfizer, Inc.*
12:30-14:00	**Hosted Lunch**	
14:00-15:05	**Session VI - Cell Therapies** 14:05-14:25 Control of Allogeneic Donor Cells and Characterization: Integrating into Cell Therapy Regulatory Strategy Amy McCord, *Takeda Pharmaceuticals* 14:25-14:45 Design Considerations in CAR-T with Novel Binding Domains Brian Murphy, *Arcellx, Inc.* 14:45-15:05 Approach to Technology Transfer in Cell Therapies Peter Gelinas, *ElevateBio, LLC*	**Panel Discussion** 15:05-15:35 Melanie Eacho, *CBER, FDA* Amy McCord, *Takeda Pharmaceuticals* Brian Murphy, *Arcellx, Inc.* Peter Gelinas, *ElevateBio, LLC*
15:35-16:20	**Networking Break**	

June 7, 2022 ***continued***		
16:20-17:20	**Roundtable Discussions** 2022 Topics – Tables 1 and 2: EMA Paper on Comparability Considerations for ATMPs - Open Discussion Table 3: Bridging Strategies for Manufacturing and CQA Assay Changes Moving from Phase 1 to Phase 2 Table 4: The Balance Between "Phase Appropriate Specifications" and Preparation for Marketing Authorization in Accelerated Developments - Lessons Learned Table 5: Challenges with Emerging Technologies for CGTP Manufacturing and Single Sourcing Table 6: Characterization of CAR-T Cell Products – Challenges and Opportunities Table 7: Developing Process Analytical Technologies (PAT) to Support Advances in Cell Therapy Manufacturing Table 8: Phase-appropriate Method Validation Table 9: Starting and Raw Materials -Harmonization Challenges, Testing and Control Requirements, etc. Table 10: Rational Setting of Vector Copy Numbers in Genetically Modified Cells	

June 8, 2022

08:30-08:45	**Welcome Day 3 & Keynote Introduction** Andrew Weiskopf, *Sana Biotechnology*	
08:45-09:45	**Keynote Presentation** FDA's Efforts to Facilitate the Development of Cell and Gene Therapies Peter Marks, *CBER, FDA*	
09:45-10:30	**Networking Break**	
10:30-11:35	**Session VII - Regulatory Session: Frameworks for Innovative Products** 10:35-10:50 Fostering Innovation in Europe: A Focus on ATMPs and CMC Considerations Within the European Regulatory System Barbara Bonamassa, *Italian Medicines Agency (AIFA)* 10:50-11:05 Advanced Therapeutic Products - An Introduction to Health Canada's Approach Michael Rosu-Myles, *Health Canada* 11:05-11:20 Indian Canvas of Cell and Gene Therapy Geeta Jotwani, *Indian Council of Medical Research* 11:20-11:35 US FDA Regulatory Considerations for Cell and Gene Therapies Kimberly Schultz, *CBER, FDA*	**Panel Discussion** 11:35-12:35 Vered Ben-Naim, *Israeli Ministry of Health* Barbara Bonamassa, *Italian Medicines Agency (AIFA)* Geeta Jotwani, *Indian Council of Medical Research* Michael Rosu-Myles, *Health Canada* Kimberly Schultz, *CBER, FDA* Marcos Timón, *Spanish Agency of Medicines and Medical Products (AEMPS)*
12:35-12:50	**Closing Remarks & Invitation to CGTP 2023** Svetlana Bergelson, *Biogen*	