5th Dec 2022

09:00-09:30	**Welcome and Introductory Comments** **CASSS Welcome and Introductory Comments** Wassim Nashabeh, *F. Hoffmann-La Roche Ltd., United States* **Welcome to the CMC Strategy Forum Japan 2022** Hiroshi Suzuki, *PMDA-Pharmaceuticals and Medical Devices Agency, Japan*
09:30-12:15	**Recent Trends in the Regulation of Biopharmaceutical Products** Session Chairs: Maria Cecilia Tami, *Genentech, a Member of the Roche Group* and Kazuhisa Uchida, *Kobe University* Session Speakers: 09:35 - 10:00 **Regulatory Updates and a Perspective on Biopharmaceuticals in Japan** Yasuhiro Kishioka, *PMDA-Pharmaceuticals and Medical Devices Agency, Japan* 10:00 - 10:25 **China's Regulatory Framework for Biological Products and the Latest Trend** Min Li, *Center for Drug Evaluation (CDE) of NMPA, China* 10:40 - 11:05 **Regulatory Considerations for Moving from Emergency Use Authorization to Biological License Application for U.S. Products** Robin Levis, *CBER, FDA, United States* 11:05 - 11:30 **FDA Perspective on Opportunities for Modernization of Regulatory Submissions** Ingrid Markovic, *CBER, FDA, United States* 11:30 - 11:55 **EMA's Support to Innovation – A Status Update** Veronika Jekerle, *European Medicines Agency, Netherlands*
12:15-13:15	**Panel Discussion** Additional Panel Members: Wu He, *Center for Drug Evaluation (CDE) of NMPA, China*
13:15-14:00	**Lunch Break**
14:00-15:05	**Stability of Biopharmaceutical Products: Topics about ICH Guideline Q1/Q5C Revision** Session Chairs: Tura Camilli, *Genentech, a Member of the Roche Group* and Hiroko Shibata, *NIHS-National Institute of Health Science* Session Speakers: 14:05 - 14:25 **Topics Regarding Revisions of ICH Q1/Q5C Guidelines: Focus on Biological Products** Takashi Kameda, *PMDA-Pharmaceuticals and Medical Devices Agency, Japan* 14:25 - 14:45 **Targeted Revision of ICH Q1s/Q5C - Opportunities with Science and Risk-based Approaches**

	Boris Zimmermann, *Genentech, a Member of the Roche Group, United States* 14:45 - 15:05 **Using Stability Prior-knowledge from 'Like-molecules' to Determine Shelf-life** Andrew Lennard, *Amgen Limited, United Kingdom*
15:05-15:35	**Panel Discussion – Questions and Answers** Additional Panel Members: Takeshi Ohmura, *Chugai Pharmaceutical Co., Ltd.*
15:35-16:00	**Mini Break**
16:00-17:15	**Visible Particles – Mechanism and Mitigation of the Formation and the Control Strategy** Session Chairs: Christof Finkler, *F. Hoffmann - La Roche Ltd.* and Akiko Ishii, *NIHS-National Institute of Health Science* Session Speakers: 16:05 - 16:25 **Perspective on Visible Particles in Biopharmaceuticals** **Yasuhiro Kishioka, Pharmaceuticals and Medical** Devices Agency, *PMDA-Pharmaceuticals and Medical Devices Agency, Japan* 16:25 - 16:45 **Proteinaceous Visible Particle in Liquid Monoclonal Antibody Formulations** Satoshi Saito, *Chugai Pharmaceutical Co., Ltd., Japan* 16:45 - 17:15 **Industry Perspective on Polysorbate Degradation and Control Strategy for Biopharmaceutical Products - A view of EFPIA Working Group** Karoline Bechtold-Peters, *Novartis Pharma AG, Switzerland* and Klaus Wuchner, *Cilag AG, Switzerland*
17:15-18:00	**Panel Discussion** Additional Panel Members: Antonia Pandelieva, *Health Canada*

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09:00-11:00	**Viral Safety of Biotechnology Products – Changing the Regulatory Landscape, Modalities and Analytical Technologies** Session Chairs: Andrew Chang, *Novo Nordisk* and Yoji Sato, *NIHS-National Institute of Health Science* Session Speakers: 09:05 - 09:30 **Concept of the ICH-Q5A Second Revision** Akira Sakurai, *PMDA-Pharmaceuticals and Medical Devices Agency, Japan* 09:30 - 09:55 **An Industry Perspective on CHO Cell Product Virus Safety** Shohei Kobayashi, *Chugai Pharmaceutical Co., Ltd., Japan* 10:10 - 10:30 **ICH Q5A (R2) Expansion of Scope to Include Viral Vectors: Application of Prior Knowledge for Adenovirus-Vectored Vaccines** Gilles Chénard, *Janssen Vaccines & Prevention B.V., Netherlands* 10:30 - 10:45 **ICH-Q5A Update and Possible Impact on Approach to Virus Clearance Study** Munehisa Masuda, *Merck Life Science* 10:45 - 11:00 **Progress of Blazar Platform with the Background of ICHQ5A R2** Huixing Feng, *Merck Life Science*
11:00-11:45	**Panel Discussion** Additional Panel Members: Christopher Storbeck, *Health Canada* Tsutomu Sugihara, *Kyowa-Kirin*
11:45-14:00	**Lunch Break**
14:00-16:25	**Cell & Gene Therapy Products – Showcase both Regulatory and CMC Issues via Case Studies and Recent Challenges Toward Solving Regulatory Issues in Japan** Session Chairs: Christiane Niederlaender, *Parexel* and Yoji Sato, *NIHS-National Institute of Health Science* Session Speakers: 14:05 - 14:30 **Global Regulatory Considerations of Allogeneic Cell Therapies** Yoko Momonoi, *Takeda Pharmaceutical Company Limited, United States* 14:30 - 14:55 **Points to Consider and Challenges in CMC for Regenerative Medical Products** Mitsuo Kitada and Naoyuki Hanada, *Novartis Pharma K.K., Japan* 14:55 - 15:20

	Composition of the Application Material on Quality for the Marketing Authorization Application of Regenerative Medical Products Atsushi Nishikawa, PMDA-Pharmaceuticals and Medical Devices Agency, Japan 15:35 - 16:00 **Current Status of GMO Regulation in Japan** Seiichi Kanzaki, *PMDA-Pharmaceuticals and Medical Devices Agency, Japan* 16:00 - 16:25 **Differences in Regulations on Gene Modified Organisms Between the Europe, Japan, and the United States** Gentaro Tajima, *Pfizer R&D Japan G.K., Japan*
16:25-17:10	**Panel Discussion** Additional Panel Members: Ryo Kondo, *AstraZeneca* Leslie Nash, *Health Canada*
17:10-17:25	**Closing Remarks** Yoshinori Kubodera, *Chugai Pharmaceutical Co., Ltd.*