FDA and Health Canada Regional ICH Consultation

February 22, 2024, 11:00 – 3:00 p.m. EST

11:00 - 11:05 PM	**Welcome** *Division of Drug Information, Center for Drug Evaluation and Research (CDER), FDA*
11:05 - 11:10 PM	**Opening Remarks** *Dr. Leo Bouthillier* *Director, Centre for Blood, Blood Products and Biotherapeutics | Biologic and Genetic Therapies Directorate | Health Products and Food Branch | Health Canada*
11:10 – 11:30 PM	**Overview of ICH** *Jill Adleberg, ICH Coordinator* *CDER, FDA*
11:30 - 12:20 PM	**<u>Updates on ICH Efficacy Related Guidelines:</u>** **M12, Drug Interaction Studies** *Kellie Reynolds, Pharm.D.* *Director, Division of Infectious Disease Pharmacology* *Office of Clinical Pharmacology, CDER, FDA* **E2D(R1), Post-Approval Safety Data Management: Definitions and Standards for for Management and Reporting of Individual Case Safety Reports** *Craig Zinderman, MD, MPH* *Associate Director for Medical Policy* *Office of Biostatistics and Pharmacovigilance, CBER, FDA* **E6(R3) Good Clinical Practice Principles and Annex 1** *Carole Légaré, MD* *Senior Advisor, Office of Clinical Trials, Pharmaceutical Directorate* *Health Products and Food Branch, Health Canada* ,
12:20 – 12:35 PM	**<u>Updates on ICH Multidisciplinary Guideline:</u>** **M14, General Principles on Plan, Design, and Analysis of Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment of Medicines** *Melissa Kampman, PhD* *Manager, Data Analytics and Real world Evidence Division* *Marketed Health Products Directorate, Health Canada*
12:35 – 12:50 PM	**Break**

12:50 – 1:40 PM **<u>Updates on ICH Quality Related Guidelines:</u>**

Q2(R2)/Q14, Revision of Q2(R1) Analytical Validation and Analytical Procedure Development
David Keire, PhD
Director, Office of Testing Research
Office of Pharmaceutical Quality, CDER, FDA

Q5A(R2), Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
Chris Storbeck, PhD, Senior Quality Evaluator
Cell, Gene Therapies, and Radiopharmaceuticals Division, Center for Oncology, Radiopharmaceuticals and Research Evaluation, Health Canada

Q9(R1), Quality Risk Management
Stephen Mahoney, MS, JD
Head of Quality Policy & Advocacy, Gilead

1:40 – 1:55 PM **<u>Updates on Other Important ICH Developments:</u>**

Cell and Gene Therapies Discussion Group
Kathleen Francissen, Ph. D., Global Head PT Cell & Gene Therapy Regulatory
Genentech, A Member of the Roche Group

2:00 – 3:00 PM **Questions & Answers Panel**

Moderated by Nick Orphanos and Jill Adleberg

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