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  Updates on ICH Efficacy Related Guidelines:  

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 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  Updates on ICH Multidisciplinary Guideline:  

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
Updates on ICH Quality Related Guidelines:

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

Updates on Other Important ICH Developments:

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

Questions & Answers Panel

Moderated by Nick Orphanos and Jill Adleberg