FDA and Health Canada Regional ICH Consultation

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

11:00 - 11:05 AM	**Welcome** *Division of Drug Information, Center for Drug Evaluation and Research (CDER), FDA*
11:05 - 11:10 AM	**Opening Remarks**
11:10 – 11:30 AM	**Overview of ICH**
11:30 - 12:20 PM	**Updates on ICH Efficacy Related Guidelines:** **M12, Drug Interaction Studies** **E2D(R1), Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting** **E6(R3) Good Clinical Practice Principles and Annex 1**
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**
12:35 – 12:50 PM	**Break**
12:50 – 1:40 PM	**Updates on ICH Quality Related Guidelines:** **Q2(R2)/Q14, Revision of Q2(R1) Analytical Validation and Analytical Procedure Development** **Q5A(R2), Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin** **Q9(R1), Quality Risk Management**
1:40 – 1:55 PM	**Updates on Other Important ICH Developments:** **Cell and Gene Therapy Reflection Paper**
2:00 – 3:00 PM	**Questions & Answers Panel** *Moderated by Nick Orphanos and Jill Adleberg*