FDA and Health Canada Regional ICH Consultation

February 24, 2023, 1:00—4:30 PM

1:00 - 1:05 PM	**Welcome** *Division of Drug Information, Center for Drug Evaluation and Research (CDER), FDA*
1:05 - 1:10 PM	**Opening Remarks**
1:10 – 1:25 PM	**Overview of ICH**
1:25-2:25 PM	**Updates on ICH Efficacy Related Guidelines:** **M11, Clinical Electronic Structured Harmonized Protocol** **M12, Drug Interaction Studies** **M13A, Bioequivalence for Immediate-Release Solid Oral Dosage Forms** **E19, A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-Approval or Post-Approval Clinical Trials**
2:25 – 2:35 PM	**Break**
2:35 – 3:15 PM	**Updates on ICH Safety Related Guidelines:** **S1B(R1), Rodent Carcinogenicity Studies for Human Pharmaceuticals and M7(R2), Assessment and Control of DNA Reactive (mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk** **S12, Biodistribution Studies for Gene Therapy Products**
3:15 – 4:00 PM	**Updates on ICH Quality Related Guidelines:** **Q5A(R2), Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin** **Q13, Continuous Manufacturing** **M10, Bioanalytical Method Validation**
4:00 – 4:30 PM	**Questions & Answers Panel**