FDA and Health Canada Regional ICH Consultation

February 24, 2023, 1:00—4:30 PM

1:00 - 1:05 PM	**Welcome** *Forest Ford* *Division of Drug Information, Center for Drug Evaluation and Research (CDER), FDA*
1:05 - 1:10 PM	**Opening Remarks** *Theresa Mullin, PhD, Associate Director for Strategic Initiatives* *CDER, FDA*
1:10 – 1:25 PM	**Overview of ICH** *Nick Orphanos, ICH Coordinator/Senior Policy Analyst* *Health Canada*
1:25-2:25 PM	**Updates on ICH Efficacy Related Guidelines:**
	M11, Clinical Electronic Structured Harmonized Protocol *Vivian Combs, MS, Senior Director and Process Owner, Clinical Trial Foundations* *Eli Lilly and Company*
	M12, Drug Interaction Studies *Rajanikanth Madabushi, PhD, Associate Director for Guidance and Scientific Policy* *Office of Clinical Pharmacology, CDER, FDA*
	M13A, Bioequivalence for Immediate-Release Solid Oral Dosage Forms *John Gordon, PhD, Senior Clinical Assessment Officer* *Division of Biopharmaceutics Evaluation, Pharmaceutical Drugs Directorate, Health Canada*
	E19, A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-Approval or Post-Approval Clinical Trials *Mary Thanh Hai, MD, Deputy Director, Clinical* *Office of New Drugs, CDER, FDA*
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
Alisa Vespa, PhD, Senior Scientific Evaluator
Pharmaceutical Drugs Directorate, Health Canada

S12, Biodistribution Studies for Gene Therapy Products
Sharon Choi, PhD, Senior Scientific Evaluator
Biologic and Radiopharmaceutical Drugs Directorate, Health Canada

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
Chris Storbeck, PhD, Senior Quality Evaluator
Gene Therapies Division, Center for Biologics Evaluation, Health Canada

Q13, Continuous Manufacturing
Sau "Larry" Lee, PhD, Deputy Director of Science
Office of Pharmaceutical Quality, CDER, FDA

M10, Bioanalytical Method Validation
Anna Edmison, PhD, Senior Clinical Assessment Officer
Division of Biopharmaceutics Evaluation, Pharmaceutical Drugs Directorate, Health Canada

4:00 – 4:30 PM **Questions & Answers Panel**

Moderated by Nick Orphanos and Jill Adleberg