FDA and Health Canada Regional ICH Consultation

February 24, 2023, 1:00—4:30 PM

1:00 - 1:05 PM **Welcome**
Forest Ford, CAPT, USPHS
Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI), 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

1:25-2:40 PM **Updates on ICH Efficacy Related Guidelines:**

M10, Bioanalytical Method Validation and Study Sample Analysis
Anna Edmison, PhD, Senior Clinical Assessment Officer
Pharmaceutical Drugs Directorate, Health Canada

M11, Clinical Electronic Structured Harmonized Protocol
Vivian Combs, MS, Advisor/Process Owner, Clinical Systems & Supply Planning
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
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

2:40 – 2:50 PM **Break**

2:50 – 3:30 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

3:30 – 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
Biologic and Radiopharmaceutical Drugs Directorate, Health Canada

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

4:00 – 4:30 PM **Questions & Answers Panel**
Moderated by Nick Orphanos and Jill Adleberg

Panelists include above speakers and:

Ron Fitzmartin, PhD, MBA
Sr. Informatics Advisor
Office of Regulatory Operations (ORO)
Center for Biologics Evaluation and Research (CBER)

Lei Zhang, PhD
Deputy Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER