US FDA and Health Canada
Regional Public Consultation on ICH

April 6, 2018, 10am to 1pm
10903 New Hampshire Ave.
Building 32 Rm 1503 (Great Room)
Silver Spring, MD 20993

10:00 - 10:05 AM	**Welcome** *Amanda Roache, MPP, Operations Research Analyst, FDA, Center for Drug Evaluation and Research (CDER), Office of Strategic Programs*
10:05 - 10:20 AM	**Overview of the ICH** *Theresa Mullin, PhD, Director, FDA, CDER, Office of Strategic Programs*
10:20 – 11:00 AM	**Topics Recently Reaching Step 3 of ICH Process** Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management *Ashley Boam, MSBE, Director, FDA, CDER, Office of Pharmaceutical Quality, Office of Policy for Pharmaceutical Quality* E9 (R1) Addendum: Statistical Principles for Clinical Trials *Thomas Permutt, PhD, Associate Director for Statistical Science and Policy, FDA, CDER, Office of Translational Sciences, Office of Biostatistics* S5(R3) Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals *Ronald Wange, PhD, Associate Director, FDA, CDER, Office of New Drugs, Pharmacology/Toxicology Staff*
11:00 – 11:30 AM	**Selected Topics Recently Reaching Step 4** E17 General Principles on planning/designing Multi-Regional Clinical Trials *Aloka Chakravarty, PhD, Director (Acting), FDA, CDER, Office of Translational Sciences, Office of Biostatistics* *Douglas Pratt, MD, MPH, Branch Chief, FDA, Center for Biologic Evaluation and Research, Office of Vaccines Research & Review, Division of Vaccines and Related Product Applications* E11(R1) Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population *Lynne Yao, MD, Director, FDA, CDER, OND, Division of Pediatric and Maternal Health*

11:30 - 11:45 AM **Update on Electronic Standards Topics and MedDRA**
Mary Ann Slack, MS, Deputy Director, Office of Strategic Programs

M2 Electronic Standards for the Transfer of Regulatory Information
M8 Electronic Common Technical Document (eCTD)
E2B Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
M1 MedDRA Terminology

11:45 – 12:00 PM **Overview of Ongoing Topics**
Amanda Roache, MPP, Operations Research Analyst, FDA, CDER, Office of Strategic Programs

E19 Optimization of Safety Data Collection
E8(R1) Revision on General Considerations for Clinical Trials
E11A Pediatric Extrapolation
E14/S7B Discussion Group on Clinical and non-Clinical Evaluation of QT/QTc Interval Prolongation
M9 Biopharmaceutics Classification System-based Biowaivers
M10 Bioanalytical Method Validation
S1(R1) Revision on Rodent Carcinogenicity Studies for Human Pharmaceuticals
S5(R3) Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals
S9 Q&A on Nonclinical Evaluation for Anticancer Pharmaceuticals
S11 Nonclinical Safety Testing in Support of Development of Pediatric Medicines
Q3C(R7) Impurities: Guideline for Residual Solvents
Q3D(R1) Guideline on Elemental Impurities

12:00 PM – 12:55 PM **Public Comment Period**

12:55 PM – 1:00 PM **Closing Remarks**