Health Canada – US FDA Regional ICH Consultation

April 3, 2019, 10am to 1pm EDT
Via Webcast (Linked below)
https://collaboration.fda.gov/fdahealthcanada/

10:00 - 10:05 AM	**Introduction** *Amanda Roache, MPP, Operations Research Analyst* *Office of the Center Director, CDER, FDA*
10:05 - 10:20 AM	**Welcome and Overview of ICH** *Joan Blair, Senior Advisor for International Affairs* *Center for Biologic Evaluation and Research, FDA*
10:20 – 11:40 AM	**Topics Recently Reaching Step 4 of ICH Process** Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management *Ashley Boam, MS, Director, Office of Policy for Pharmaceutical Quality, CDER, FDA* E9(R1): EWG Addendum: Statistical Principles for Clinical Trials *Dr. Catherine Njue, Biostatistics Advisor for Clinical Trials* *Biologic and Radiopharmaceutical Drugs Directorate, Health Canada* M9: Biopharmaceutics Classification System-based Biowaivers *Dr. Mehul Mehta, Director, Division of Neuropsychiatric Pharmacology* *Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA* S5(R3): Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals *Dr. Ron Wange, Acting Associate Director for Pharmacology & Toxicology* *Office of New Drugs, CDER, FDA*
11:40 – 12:10 PM	**Update on Electronic Standards Topics and MedDRA** *Mary Ann Slack, MS, Director* *Office of Strategic Programs, CDER, FDA* ▪ M1 PtC WG: MedDRA Points to Consider ▪ M2 EWG: Electronic Standards for the Transfer of Regulatory Information (ESTRI) ▪ M11 Clinical electronic Structured Harmonised Protocol ▪ E2B Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports ▪ M8 Electronic Common Technical Document (eCTD)

12:10 - 12:40 PM **Overview of Ongoing Topics**
Amanda Roache, MPP, Operations Research Analyst
Office of the Center Director, CDER, FDA

12:40 PM - 12:55 PM **Questions**

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