US FDA and Health Canada Regional ICH Consultation

October 19, 2017, 9am to 12pm
Sir Frederick G. Banting Research Centre
251 Sir Frederick Banting Driveway, Ottawa, Ontario

9:00 - 9:05 AM	**Opening Remarks** *Celia Lourenco* *Director Generals Office, Therapeutic Products Directorate*
9:05 - 9:15 AM	**Overview of the ICH Process and New Topics** *Celia Lourenco* *Director Generals Office, Therapeutic Products Directorate*
9:15 - 9:30 AM	**Expert Working Groups to Begin in Geneva** E19: Optimisation of Safety Data Collection *Fannie St-Gelais* *Bureau of Cardiology, Allergy and Neurological Sciences, Therapeutic Products Directorate*
9:30 - 10:10 AM	**Topics Under Consultation (Step 2 of ICH Process)** S5(R3): Detection of Toxicity to Reproduction for Human Pharmaceuticals *Rajkumar Kadaba* *Bureau of Gastroenterology, Infection and Viral Diseases, Therapeutic Products Directorate* E9(R1): Defining Appropriate Estimand for a Clinical Trial/Sensitivity Analyses *Catherine Njue* *Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate*
10:10 - 11:10 AM	**Selected Topics Recently Reaching Step 4** Q11 Q&A: Selection and Justification of Starting Materials for the Manufacture of Drug Substances *Gary Condran* *Bureau of Pharmaceutical Sciences, Biologics and Genetic Therapies Directorate* E11(R1): Paediatric Drug Development *Ariel Arias* *Centre for Biologics Evaluation, Biologics and Genetic Therapies Directorate* E18: Genomic Sampling and Management of Genomic Data *Agnes Klein* *Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies Directorate*

11:10 – 11:40 AM **Question Period: Ongoing Topics**

E17: Multi-Regional Clinical Trials

E14/S7B: Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drug

M9: Biopharmaceutics Classification System-based Biowaivers

M10: Bioanalytical Method Validation

S1(R1): Revision on Rodent Carcinogenicity Studies for Human Pharmaceuticals

S3A Q&A: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure - Focus on Microsampling

S9 Q&A: Nonclinical Evaluation for Anticancer Pharmaceuticals

S11: Nonclinical Safety Testing in Support of the Development of Paediatric Medicines

Q3C(R7): Impurities: Guideline for Residual Solvents

Q3D(R1): Impurities: Guideline on Elemental Impurities

Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

MedDRA and MedDRA Points to Consider

11:40 - 11:55 AM **Update on Electronic Standards Topics**
Vikesh Srivastava
Resource Management and Operations Directorate
Information Management and Technology

M2: Electronic Standards for the Transfer of Regulatory Information
M8: Electronic Common Technical Document: eCTD
E2B: Electronic Submission of ICSRs

11:55 AM – 12:00 PM **Closing Remarks**