US FDA and Health Canada
Regional Public Consultation on ICH

April 29, 2019, 10am to 1pm
10903 New Hampshire Ave.,
Bldg. 31 Rm. 1503 (Great Room),
Silver Spring, MD 20993-0002, U.S.A.

10:00 - 10:05 AM **Welcome**
William Lewallen, Project Specialist
Office of the Center Director, Center for Drug Evaluation and Research (CDER),
US Food and Drug Administration (FDA)

10:05 - 10:20 AM **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 3 of the ICH Process**

E8(R1) Revision on General Considerations for Clinical Trials
Lisa LaVange, PhD, Professor and Associate Chair
Department of Biostatistics, University of North Carolina

E19 Optimization of Safety Data Collection
Mary Thanh Hai, MD, Director
Office of Drug Evaluation II, Office of New Drugs, CDER, FDA

S11 Nonclinical Safety Testing in Support of Development of Paediatric Medicines
Karen Davis Bruno, PhD
Office of New Drugs, CDER, FDA

M10 Bioanalytical Method Validation
Brian Booth, PhD, Deputy Director
Division of Clinical Pharmacology V, Office of Translational Sciences, 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

- E2B(R3) Revision of the Electronic Submission of Individual Case Safety Reports
- M8 Electronic Common Technical Document (eCTD)
- M2 Electronic Standards for the Transfer of Regulatory Information (ESTRI)
- M1 MedDRA Points to Consider

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

- E9(R1) Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses
- E11A Pediatric Extrapolation
- E14/S7B The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
- E17 Multi-Regional Clinical Trials
- M9 Biopharmaceutics Classification System-based Biowaivers
- M7(R2): Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities In Pharmaceuticals To Limit Potential Carcinogenic Risk
- M11 Clinical electronic Structured Harmonized Protocol (CeSHarP)
- S1(R1) Revision on Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline
- S5(R3) Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals
- Q3C(R8) Maintenance of the Guideline for Residual Solvents
- Q3D(R1)/(R2) Maintenance of the Guideline for Elemental Impurities
- Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
- Q13 Continuous Manufacturing
- Q2(R2)/Q14 Analytical Procedure Development and Revision of Q2(R1) Analytical Validation

12:40 PM - 12:55 PM **Public Comment Period**

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