Joint US FDA – Health Canada ICH Public Meeting 2025

February 11th: 11:00 AM – 3:00 PM ET

11:00 - 11:05 AM	**Welcome** **Kori Adair, PharmD** *Pharmacist* CDER Small Business and Industry Assistance (SBIA) Division of Drug Information (DDI) | Office of Communications (OCOMM) Center for Drug Evaluation and Research (CDER) Food and Drug Administration (FDA)
11:05 - 11:10 AM	**Opening Remarks** **Theresa M Mullin, PhD** *Associate Center Director - Strategic Initiatives* CDER | FDA
11:10 – 11:30 AM	**Overview of ICH** **Nick Orphanos** *ICH Coordinator/Senior Policy Analyst* Pharmaceutical Drugs Directorate Health Canada (HC)
11:30 - 12:30 PM	**<u>Updates on ICH Efficacy Guidelines:</u>** **E6(R3): Good Clinical Practice Annex 2** **Carole Légaré, MD** *Senior Advisor* Office of Clinical Trials Pharmaceutical Drugs Directorate Health Products and Food Branch | HC **E11A: Paediatric extrapolation** **Lynne Yao, MD** *Director Division of Pediatrics and Maternal Health (DPMH)* Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM) Office of New Drugs (OND) | CDER | FDA

12:30 – 1:30 PM **Updates on ICH Multidisciplinary Guideline:**

M13A, M13B: Bioequivalence for Immediate-Release Solid Oral Dosage Forms
Lei Zhang, PhD
Deputy Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) | CDER

M15: General Principles for Model-Informed Drug Development
Scott Marshall
PhRMA

1:30 – 1:50 PM **Break**

1:50 – 2:20 PM **Updates on ICH Quality Guidelines:**

Q1/Q5C: Targeted Revisions of the ICH Stability Guideline Series
Paula Russell
Senior Biologist/Evaluator
Biologic and Radiopharmaceutical Drugs Directorate
Health Products and Food Branch | HC

2:20 – 3:00 PM **Questions & Answers Panel**

Moderated by Nick Orphanos and Jill Adleberg

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