US FDA and Health Canada Regional
ICH Consultation
24 April 2017, 11am to 2pm
FDA White Oak Campus, 10903 New Hampshire Ave.
Building 31, Rm 1503A, Silver Spring, MD 20993

11:00 - 11:15 AM  Opening Remarks and Overview of the ICH Process
Amanda Roache, FDA, Center for Drug Evaluation and Research (CDER), Office of Strategic Programs

11:15 - 11:35 AM  Overview of Current Quality Topics
Ashley Boam, Director, FDA, CDER, Office of Pharmaceutical Quality, Office of Policy for Pharmaceutical Quality
Q&A

11:35 - 11:55 AM  Overview of Current Efficacy Topics
Ariel Arias, MD, PhD, Senior Advisor, Health Canada, Centre for Biologics Evaluation, Biologics and Genetic Therapies Directorate
Q&A

11:55 - 12:15 PM  Overview of Current Safety Topics
Karen Davis Bruno, Ph.D, Associate Director Pharmacology & Toxicology, FDA, CDER, Office of New Drugs
Q&A

12:15 – 12:35 PM  Overview of MedDRA and MedDRA Points to Consider
Christopher Breder, MD, PhD, Medical Officer, FDA, CDER, Office of New Drugs
Q&A

12:35 - 12:55 PM  Overview of Current Electronic Standards Topics
Mary Ann Slack, Deputy Director, FDA, CDER, Office of Strategic Programs
Q&A

12:55 – 1:15  Industry Perspective on ICH
Jerry Stewart, Deputy Vice President, Scientific and Regulatory Advocacy, PhRMA
Q&A

1:15 – 1:35 PM  ICH Strategic Discussions: Modernization of ICH E8 and Subsequent Renovation of ICH E6
Theresa Mullin, PhD, Director, Office of Strategic Programs, Center for Drug Evaluation and Research, FDA
Q&A

1:35 – 1:55 PM  Public Comment

1:55 – 2:00 PM  Closing Remarks