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**