
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 Theresa Mullin, PhD, Director, 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