US FDA/Health Canada Regional
ICH Public Consultation

6 May 2016, 9am to 12pm

FDA White Oak Campus, Building 31, CR 1503A

9:00 - 9:10 AM	**Opening Remarks and ICH Overview** Theresa Mullin, Director, Office of Strategic Programs, Center for Drug Evaluation and Research, FDA
9:10 - 9:30 AM	**Overview of the ICH Process and ICH Reforms** Cathy Parker, Director General, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada
9:30 – 9:35 AM	**Q&A Session**
9:35 - 9:55 AM	**Overview of MedDRA and MedDRA Points to Consider** Christopher Breder, Medical Officer, Office of New Drugs, Center for Drug Evaluation and Research, FDA
9:55 – 10:00 AM	**Q&A Session**
10:00 - 10:20 AM	**Overview of Current Efficacy Topics** Jocelyn Ulrich, Assistant Vice President, Science and Regulatory Advocacy, PhRMA
10:20 - 10:25 AM	**Q&A Session**
10:25 - 10:45 AM	**Overview of Current Safety Topics** Karen Davis Bruno, Associate Director, Office of New Drugs, Center for Drug Evaluation and Research, FDA
10:45 - 10:50 AM	**Q&A Session**
10:50 - 11:10 AM	**Overview of Current Quality Topics** Moheb Nasr, Vice President, GlaxoSmithKline, CMC Regulatory Strategy
11:10 - 11:15 AM	**Q&A Session**
11:15 - 11:35 AM	**Overview of Current Electronic Standards Topics** Mary Ann Slack, Deputy Director, Office of Strategic Programs, Center for Drug Evaluation and Research, FDA
11:35 – 11:40 AM	**Q&A Session**
11:40 – 11:50 AM	**Public Presentations**
11:50 – 12:00 PM	**Closing Remarks** Theresa Mullin, Director, Office of Strategic Programs, Center for Drug Evaluation and Research, FDA