FDA and Health Canada Regional ICH Consultation
May 11, 2021, 1:00—4:00 PM

1:00 - 1:05 PM  Welcome
Ray Ford, PharmD, BCPS
Captain | United States Public Health Service
CDER Small Business and Industry Assistance Program (CDER SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

1:05 - 1:10 PM  Opening Remarks
Theresa Mullin, PhD,
Associate Director for Strategic Initiatives
CDER|FDA

1:10 – 1:25 PM  Overview of ICH
Jill Adleberg,
ICH Coordinator
Office of the Center Director (OCD)|CDER|FDA

1:25-2:30 PM  Topics Recently Reaching Milestones:
E11A, Paediatric Clinical Trials Extrapolation
Lynne P. Yao, MD
Director
Division of Pediatric and Maternal Health (DPMH)|CDER|FDA

Q9(R1), Quality Risk Management
TBD

Q2/Q14, Analytical Validation
Muhammad Shahabuddin, PhD
Chief, Laboratory of Biochemistry, Virology and Immunochimistry
Division of Biological Standards and Quality Control (DBSQC),
Office of Compliance and Biologics Quality (OCBQ)|CBER|FDA

2:30 – 2:45 PM  Break
2:45 – 3:30 PM  
**Topics Recently Reaching Milestones, Continued**

**E14/S7B, Clinical Evaluation of Qt/QTc Interval Prolongation and Proarrhythmic Potential**  
*QnA*

*David Strauss, MD, PhD*  
*Director*  
Division of Applied Regulatory Science (DARS)  
Office of Translational Science (OTS) | CDER | FDA

**Q3D(R3), Revision for Cutaneous and Transdermal Products**  
*Alisa Vespa, PhD*  
*Senior Scientific Evaluator*  
Therapeutic Products Directorate | Health Canada

3:30 – 4:00 PM  
**Questions & Answers Panel**