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## 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 Immunochemistry*  
Division of Biological Standards and Quality Control (DBSQC),  
Office of Compliance and Biologics Quality (OCBQ)|CDER|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**