FDA and Health Canada Regional
ICH Consultation
May 11, 2022, 1:00—4:00 PM

1:00 - 1:05 PM
Welcome
Renu Lal, PharmD, BCACP
Lieutenant Commander, United States Public Health Service
Team Lead – Division of Drug Information (DDI)
Deputy Director, SBIA
Division of Drug Information (DDI) | Office of Communications (OCOMM)
CDER | 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
Rick Friedman
Deputy Director
Office of Manufacturing Quality | CDER | FDA

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) | 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**

*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**

*Joining the panel in Rick Friedman’s stead is:*

*Alexey Khrenov, PhD*

CMC Reviewer  
Office of Tissues and Advanced Therapies | CBER | FDA