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	**<u>Topics Recently Reaching Milestones:</u>** **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 **<u>Topics Recently Reaching Milestones, Continued</u>**

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**

Joining the panel in Rick Friedman's stead is:
Alexey Khrenov, PhD
CMC Reviewer
Office of Tissues and Advanced Therapies | CBER | FDA