FDA and Health Canada Regional ICH Consultation

May 14, 2021, 1 pm to 4 pm EDT

1:00 - 1:05 PM	**Welcome** *CDER's SBIA Designee*
1:05 - 1:10 PM	**Opening Remarks** *Theresa Mullin, PhD, Associate Director for Strategic Initiatives* *FDA Center for Drug Evaluation and Research (CDER)*
1:10 – 1:20 PM	**Overview of ICH** *Jill Adleberg, ICH Coordinator* *Office of the Center Director, CDER, FDA*
1:20 – 1:50 PM	**Topics Recently Reaching ICH Milestones (S1 and Q3C)** *Alisa Vespa, PhD, Senior Scientific Evaluator* *Therapeutic Products Directorate, Health Canada*
1:50 – 2:20 PM	**E6 Principles** *Khair ElZarrad, PhD, MPH, Deputy Director* *Office of Medical Policy, CDER, FDA*
2:20 - 2:40 PM	**Q12 Implementation** *Ashley B. Boam, Director* *Office of Policy for Pharmaceutical Quality, CDER, FDA*
2:40 – 2:50 PM	**Break**
2:50 – 3:10 PM	**Model Informed Drug Development** *Scott Marshall, PhD, Senior Director* *Pfizer*
3:10 - 3:25 PM	**Patient Focused Drug Development** *Robyn Bent, RN, MS* *Director, Patient-Focused Drug Development Program* *Office of the Center Director, CDER, FDA*
3:25 – 4:00 PM	**Questions & Answers Panel** All Webinar Speakers