Health Canada Santé Canada

APEC Asia-Pacific Economic Cooperation

ICH Recognised Training Programme

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

ICH GCP and MRCT Training: ICH E6(R2) and ICH E17

When: February 26-28, 2019

Where: John G. Diefenbaker Building (Old City Hall) – 111 Sussex Drive, Ottawa, Ontario

What: Didactic and Case-based learning, presentations, and open discussion

Who: Regulators from Health Canada (reviewers and inspectors), and individuals from industry, academia, and non-profit organizations

Learning Objectives:

- Describe the standards of Good Clinical Practice (GCP) and key considerations in Multi-Regional Clinical Trials (MRCTs) design as set out in ICH E6(R2) and ICH E17 guidance, with particular focus on how the guidelines are applied by Health Canada.
- Use case studies, to apply the changes of ICH E6(R2) addendum and ICH E17 to increase the acceptability of MRCT data by multiple regulatory authorities
- Demonstrate practical approaches that Health Canada may take to fulfill the requirements of ICH E6(R2) and ICH E17 consistent with ICH standards

For Regulators:

- Describe and demonstrate best practices to assess clinical trial regulatory submissions by Health Canada, including study design, data packages, essential documents, reports, and filings for alignment with ICH GCP and MRCT
- Describe inspection methodologies that may be taken by Health Canada to assess clinical trial conduct for alignment with ICH GCP and MRCT standards, including review of corrective actions.

For other Stakeholders:

- Gain better understanding and knowledge of Health Canada expectations with regards to compliance with the Canadian clinical trial regulations and GCP inspection processes

Application opened in January 2019 | For more information see attached application form
No registration costs. Open to all APEC economies.