DIA Learning

ICH Recognised Training Programme

# ICH Clinical Safety and Efficacy Stream

**October 16 | 8:00AM-5:00PM | Ottawa, Ontario, Canada**

**INSTRUCTORS**


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## Overview

The International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner.

Harmonization is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side. The key to the success of this process is the commitment of the ICH regulators to implement the final Guidelines.

This introductory training course will provide an overview of the ICH process, the value that ICH brings to drug regulation in Canada, as well as ICH clinical safety and efficacy guidelines.

## What You Will Learn

- How ICH works
- Regulatory requirements in line with ICH guidelines in Canada
- Approaches to ICH guideline development and implementation in Canada
- Why ICH is of such value to Health Canada
- Good clinical practice
- Defining appropriate estimand for a clinical trial/sensitivity analyses
- Pediatric drug development
- Multi-regional clinical trials
- Pharmacogenomics
- Nonclinical evaluation for anticancer pharmaceuticals
- Assessment and control of DNA reactive impurities

## Who Should Attend

Professionals who work in:

- Regulatory affairs
- Clinical development/clinical sciences
- Drug safety
- Pharmacoepidemiology
- Project management

## Learning Objectives

At the conclusion of this short course, participants should be able to:

- Evaluate the ICH process and how ICH guidelines are developed and implemented in Canada
- Discuss the value that ICH brings to drug regulation in Canada
- Describe key ICH quality guidelines
- Identify how and when to use the guidelines throughout the life cycle

# Agenda

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## MONDAY, OCTOBER 16

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| **8:00AM-5:00PM** | **Registration** |
| **8:00-8:30AM** | Continental Breakfast and Networking |
| **8:30-9:30AM** | **ICH Introduction**<br>• General ICH Update and Overview<br>• ICH Return on Investment Project |
| **9:30-10:30AM** | **Risk Management Planning and E2C: PBRER/PSUR Review in Canada** |
| **10:30-11:00AM** | Refreshment and Networking Break |
| **11:00AM-12:00PM** | **E9: Addendum to Defining Appropriate Estimand for a Clinical Trial/ Sensitivity Analyses** |
| **12:00-1:00PM** | Luncheon and Networking |
| **1:00-2:00PM** | **M4E(R2): Enhancing the Format and Structure of Benefit-Risk Information in ICH**<br>**S9: Nonclinical Evaluation for Anticancer Pharmaceuticals** |
| **2:00-3:00PM** | **E11: Addendum to Pediatric Drug Development** |
| **3:00-3:15PM** | Refreshment and Networking Break |
| **3:15-4:15PM** | **E15, E16 & E18: Pharmacogenomics** |
| **4:15-5:00PM** | **Q&A and Wrap-Up** |