DIA Learning

ICH Recognised Training Programme

Quality Stream

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

INSTRUCTORS

Celia Lourenco, PhD
Director, Bureau of Gastroenterology Infection and Viral Diseases
Health Canada

Nick Orphanos
Senior Policy Analyst
Health Canada

Sonia Myers
Team Leader
Health Canada

Krishnan Tirunellai, PhD
Senior Scientific Advisor
Health Canada

Alison Ingham, PhD
Team Leader, Generic Drugs Quality Division
Health Canada

Alisa Vespa, PhD
Assessment Officer
Health Canada

Amirthini Rajkumar, PhD
Team Leader/ Advisor
Health Canada

Stephen McCaul
Drug Inspection Supervisor, Regulatory Operations and Regions Branch
Health Canada

Gary Condran
Associate Director
Health Canada

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 quality 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
- Drug impurities
- Pharmaceutical quality risk management
- Pharmaceutical quality systems
- Selection and justification of starting materials for the manufacture of drug substances
- Technical and regulatory considerations for pharmaceutical product life cycle management

Who Should Attend

Professionals who work in:

- Drug safety
- Quality
- Pharmacoepidemiology
- Regulatory affairs
- Clinical development/clinical sciences
- 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	
8:00AM-5:00PM	**Registration**
8:00-8:30AM	Continental Breakfast and Networking
8:30-9:30AM	**ICH Introduction** • General ICH Update and Overview • ICH Return on Investment Project
9:30-10:30AM	**Q3C: Impurities: Guideline for Residual Solvents** **Q3D: Impurities: Guideline for Elemental Impurities**
10:30-11:00AM	Refreshment and Networking Break
11:00AM-12:00PM	**M7: Assessment and Control of DNA Reactive Impurities**
12:00-1:00PM	Luncheon and Networking
1:00-2:00PM	**Q9: Application of Quality Risk Management in Product Life Cycle: From Product Development to Post-Approval Changes**
2:00-3:00PM	**Q10: Pharmaceutical Quality System**
3:00-3:15PM	Refreshment and Networking Break
3:15-4:15PM	**Q11: Questions and Answers Document: Selection and Justification of Starting Materials for the Manufacture of Drug Substances**
4:15-5:00PM	**Q&A and Wrap-Up**