Clinical Research and Drug Safety Certificate (Online)

Certificate Program Overview

The *Clinical Research and Drug Safety Certificate Program* provides with knowledge and insight into the most recent developments in clinical research, drug development and pharmacovigilance. Students will learn Good Clinical Practices (GCP), regulatory framework of drug development, organization and management of clinical studies conducted across multiple phases to assess the safety and effectiveness of medicinal products, and current pharmacovigilance methodologies.

The program focuses on topics delivered through five modules:

- An overview of the entire drug development process in Canada and the scope and functioning of a pharma company Main steps of the drug development process, from drug discovery, and preclinical animal testing to all phases of clinical research and post-approval drug safety surveillance The regulation of drug development is based on principles of safety, efficacy, and quality, including Good Clinical Practice (GCP) is a set of principles that govern the conduct of clinical trials. Clinical trial administration and ways of monitoring ensuring that data and supporting documentation integrity.
- Key concepts for clinical trial project management Advanced medical and technical writing necessary to develop the clinical study Protocol and ICF

A well-trained and knowledgeable Clinical Research and Drug Safety professional plays a vital role in protecting the study participant and the general population for marketed drugs and in helping to reduce the time between drug development and marketing approval.

Certificate Program Outline

Successful candidates will also receive certificate per completed module:

- The Canadian Pharmaceutical Industry: Big Picture
- Introduction to Clinical Research and Drug Safety
- Clinical Research Regulations and Good Clinical Practices (GCP)
- Organization of Clinical Trials and Clinical Monitoring Plan Development
- Clinical Project Management and Project Chart Development
- Clinical Study Protocol and ICF Development

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Program Details

Program Tuition Fees	Duration	Mode
CAD $3,300	11 Weeks	Online

Course Outline

	Course	Code	Cost
1	The Canadian Pharmaceutical Industry: Big Picture	CR09	CAD $595
2	Introduction to Clinical Research and Drug Safety	CR010	CAD $650
3	Clinical Research Regulations and Good Clinical Practices (GCP)	CR014	CAD $650
4	Organization of Clinical Trials and Clinical Monitoring Plan Development	CR019	CAD $650
5	Clinical Project Management and Project Chart Development	CR020	CAD $695
6	Clinical Study Protocol and ICF Development	CR025	CAD $650