CHARTERED
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CANADA CLINICAL TRIAL REGULATIONS AND COMPLIANCE

Fully Accredited By:

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CPD Certification Service

PROGRAM OVERVIEW

According to a survey by the Canadian Clinical Trials Coordinating Centre, **72% of clinical leaders cited significant challenges when conducting clinical trials in Canada due to complex regulatory requirements, overwhelming documentation and stringent approvals**.

This certified program will provide you with a thorough overview of the regulatory landscape, covering essential frameworks such as the **Food and Drugs Act, Good Clinical Practice (GCP) guidelines, and ICH E6 (R2) standards**. Participants will gain valuable insights into the **Clinical Trial Application (CTA) process**, from initial preparation through submission and approval. You will also gain insights into the **intricate requirements for documentation and safety reporting protocols, adverse event reporting protocols as well as the impacts of non-compliance** in clinical trials.

Throughout the program, participants will learn to navigate **Health Canada's specific clinical trial requirements, comply with Research Ethics Board procedures and implement effective informed consent protocols** to ensure the highest ethical standards are maintained. Furthermore, this program will equip you with practical skills to **integrate these regulations into clinical trial design and management**, ensuring compliance and ethical conduct throughout the trial process. This includes understanding the **complexities of multi-provincial trials within Canada and adapting to evolving regulatory requirements**. Additionally, you will also gain insights into effective data management and safety reporting techniques along with robust safety management plans that mitigate potential safety concerns.

Upon successful completion, you will receive the **Certification in Canada Clinical Trial Regulations and Compliance**, demonstrating their proficiency in navigating Canada's clinical research landscape. This industry-recognized certification not only enhances professional credentials but also showcases a commitment to maintaining the highest standards of clinical trial conduct in Canada.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

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KEY SKILLS YOU WILL GAIN

From This Program

CLINICAL TRIAL REGULATORY FRAMEWORK
CLINICAL TRIAL APPLICATION (CTA) PROCESS
HEALTH CANADA'S LEGISLATION FRAMEWORK
INFORMED CONSENT AND ETHICS REVIEW EXPERTISE

GOOD CLINICAL PRACTICE (GCP) COMPLIANCE
REGULATORY SUBMISSION PROCEDURES
POST-MARKETING SURVEILLANCE
REGULATORY INSPECTION MANAGEMENT

GLOBAL REGULATORY STRATEGY
INVESTIGATOR'S BROCHURE (IB)
INFORMED CONSENT FORM (ICF)
GCP COMPLIANCE: ICH E6(R2)

STANDARD OPERATING PROCEDURES (SOPS)
ADVERSE EVENT (AE) REPORTING
SERIOUS ADVERSE EVENT (SAE)
RESEARCH ETHICS BOARD (REB) STANDARDS
FOOD AND DRUG REGULATIONS (FDR)

QUALITY ASSURANCE (QA)
QUALITY CONTROL (QC)

YOUR FACULTY DIRECTOR

Jordan John

Distinguished Regulatory Affairs & Quality Management Expert

Jordan John is a **distinguished leader in regulatory affairs, compliance, and quality management, with over a decade of experience in navigating complex regulatory landscapes**. Currently, he serves as the Director of Regulatory Affairs, Compliance & Quality where he oversees compliance with FDA, EU, Health Canada, TGA, PMDA, and other international regulations.

As an **Advisory Board Member at Humber College since April 2024**, Jordan contributes strategic insights to clinical regulatory and compliance education. He also served as a **Professor, developing and lecturing in regulatory affairs and quality assurance programs**. His previous roles include Senior Regulatory Affairs at Fio Corporation, where he led IVD/device submissions to Health Canada, FDA, and other jurisdictions, and Regulatory Affairs Specialist and Consultant at Southmedic Inc., where he developed regulatory strategies and led audits and QA projects.

Jordan's comprehensive knowledge and experience make him an invaluable asset in the field of regulatory affairs and compliance, ensuring the highest standards of quality and safety in clinical trials and medical device management.

OUR PARTICIPANTS

Over 70% of FORTUNE 500 Companies Have Attended Our Accredited Programs Before

PROGRAM AGENDA

MODULE 1 - OVERVIEW OF HEALTH CANADA'S REGULATORY FRAMEWORK

- Key Legislations (Food and Drugs Act, Regulations) and Importance of Compliance
- Core Principles of GCP; Investigator and Sponsor Responsibilities; Implementing GCP in Clinical Trials

MODULE 2 - GOOD CLINICAL PRACTICE (GCP)

- Core Principles of GCP and Investigator/ Sponsor Responsibilities
- Implementing GCP in Clinical Trials

MODULE 3 - CLINICAL TRIAL APPLICATION (CTA) PROCESS

- Components of a CTA
- Submission/ Review Process and its Common Pitfalls
    - Investigator Roles; Site Selection and Management; Training and Oversight

MODULE 4 - INFORMED CONSENT AND ETHICS REVIEW

- Role of Research Ethics Boards (REBs)
- Informed Consent Process
- Ethical Guidelines and Participant Protection

MODULE 5 - ADVERSE EVENT REPORTING AND SAFETY MONITORING

- Identifying Adverse Events AEs and Serious Adverse Events (SAEs)
    - Case Study: Delayed AE Reporting Consequences
- Reporting Requirements and Timelines
- Effective Communication with Health Canada and REBs, Reporting Requirements and Best Practices
- Key Elements of a Clinical Trial Protocol and Ensuring Protocol Adherence
- Identifying Potential Risks; Risk Mitigation Strategies; Monitoring Risks

MODULE 6 - CLINICAL TRIAL INSPECTIONS AND AUDITS

- Quality Management Systems
- Internal Audits
- Continuous Improvement
- Preparing for Inspections; Conducting Mock Inspections; Addressing Findings

MODULE 7 - CLINICAL TRIAL RECORDS AND DATA MANAGEMENT

- Ensuring Data Accuracy and Reliability
- Best Practices for Data Collection and Storage
- Handling Discrepancies

PROGRAM AGENDA

MODULE 8 - REGULATORY COMPLIANCE

- Oversight of Trial Conduct
- Ensuring Regulatory Compliance
  - Sponsor Roles and Responsibilities
  - Ensuring Compliance
  - Learning From Sponsor Non-Compliance Issues
- Case Study: Sponsor Non-Compliance

MODULE 9 - MANAGEMENT OF DEVIATIONS

- Identifying and Documenting Deviations, Assessing Impacts and Corrective and Preventive Actions
- Monitoring Participant Safety, Managing Adverse Events and Ongoing Informed Consent

MODULE 10 - RISK MANAGMENT

- Investigator Roles
  - Site Selection and Management
  - Training and Oversight
- Types of Monitoring
  - Conducting Audits
  - Continuous Compliance
- Reviewing AE Reporting and Protocol Deviations
  - Group Discussion
  - Developing Action Plans
- Best Practices for Documentation
  - Ensuring Accuracy and Completeness
  - Handling Inspections

MODULE 11 - EMERGING TRENDS

- Staying Current With Regulations
- Implementing Updates and Communicating Changes
- Recap of Key Points; Participant Questions; Training Evaluation

YOUR CHARTER DESIGNATION

Chartered Institute of Professional Certifications' programs are unique as they provide you with professional charter designations and marks that can be used across your lifetime once you have completed our programs.

Upon successfully completing this program, you will be awarded the **Certification in Canada Clinical Trial Regulations and Compliance**, which can be included in your resume, CV, and other professional credentials. This industry-recognized certification holds lifelong validity.

Globally sought-after and respected, this certification will elevate your professional qualifications and demonstrate your expertise in clinical trial regulations, compliance, and safety protocols within the Canadian regulatory framework. Developed by the **Chartered Institute of Professional Certifications**, the program content has been independently accredited by the **CPD Certification Service**, ensuring it adheres to the highest standards of continuing professional development principles.

ABOUT US

49,525 Business Leaders Have Attained Their Chartered Certifications Since 2009

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Chartered Institute of Professional Certifications

All of Chartered Institute of Professional Certifications programs are fully accredited programs. The professional charters and designations are trademarked credentials that can only be used by professionals who have completed and passed our accredited program. It is also independently accredited by CPD as adhering to the highest standards of continuing professional principles.

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OUR FACULTY DIRECTORS

We Collaborate With Instructors From Renowned Institutions

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CONTACT US TODAY

We Thank You for Your Ongoing Support of Our Programs

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