CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

CERTIFIED CANADA GOOD CLINICAL PRACTICE MANAGER™

CGCP ™

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

Robust GCP compliance is non-negotiable in Canada, where over 900 clinical trials are authorized annually and inspection findings frequently cite documentation gaps and protocol deviations. **Non-compliance can delay approvals, trigger costly remediation, or halt trials entirely**. With global sponsors prioritizing high-quality, inspection-ready data, strong GCP capability is essential to protect participants, secure data integrity, and maintain Canada's standing as a trusted clinical research hub.

This certified program is built to equip you with a comprehensive and practical command of Canada's clinical trial regulatory framework and GCP requirements across the full study lifecycle. You will develop authoritative expertise in **ICH E6 (R2) and emerging R3 expectations, Clinical Trial Applications (CTA), Research Ethics Board (REB) processes, informed consent, and participant protection**—enabling you to navigate regulatory requirements with confidence and make informed, compliant decisions in real-world trial settings. By integrating Canadian-specific requirements—including **Health Canada submissions, review processes, and ethical standards**—the program ensures you can apply global GCP principles effectively within the local regulatory landscape.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

PROGRAM OVERVIEW

The program also strengthens your ability to implement and lead compliant clinical trial operations. You will develop the practical skills required to **design high-quality, inspection-ready protocols aligned with ICH E6 and E8**, implement risk-based quality management (RBQM) to drive efficiency and oversight, and maintain robust Trial Master Files (TMFs) that support audit readiness. You will further enhance your capabilities in **safety reporting, CAPA management, deviation handling, vendor oversight, and monitoring strategies**—empowering you to proactively identify risks, secure data integrity, and ensure consistent regulatory compliance. By the program's end, you will be fully prepared to lead GCP-compliant trials with confidence, optimize operational performance, and command regulatory inspections and audits.

Upon completing the program and passing the Chartered exam, you will earn the **Certified Canada Good Clinical Practice Manager (CGCP™)** designation. This industry-recognized credential validates your expertise in ICH E6 Good Clinical Practice, Canadian clinical trial regulations, and GCP compliance systems—positioning you as a trusted professional ready to lead compliant clinical trials, strengthen regulatory oversight, and deliver inspection-ready, high-quality research operations.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

KEY SKILLS YOU WILL GAIN

From This Program

- CANADA GCP COMPLIANCE
- ICH E6 (R2/R3) IMPLEMENTATION
- HEALTH CANADA DIVISION 5 COMPLIANCE
- CLINICAL TRIAL APPLICATIONS (CTA) PREPARATION
- NO OBJECTION LETTER (NOL) PROCESS
- ETHICAL CLINICAL RESEARCH CONDUCT
- RESEARCH ETHICS BOARD (REB) COORDINATION
- CRO AND VENDOR OVERSIGHT
- QUALIFIED INVESTIGATOR (QI) COMPLIANCE
- PROTOCOL DEVELOPMENT AND DESIGN
- RISK-BASED QUALITY MANAGEMENT (RBQM)
- QUALITY MANAGEMENT SYSTEMS (QMS)
- TRIAL MASTER FILE (TMF) GOVERNANCE
- ESSENTIAL DOCUMENTS MANAGEMENT
- DATA INTEGRITY (ALCOA+)
- ELECTRONIC DATA SYSTEMS (EDC/ECOA/ESOURCE)
- PHARMACOVIGILANCE AND SAFETY REPORTING

YOUR FACULTY DIRECTOR

Dr. Yatika Kohli

Global GCP Leader in Clinical Trial Strategy and Regulatory Excellence

Dr. Yatika Kohli is a highly accomplished clinical research and regulatory leader with over 23 years of global experience across the biotechnology and pharmaceutical sectors. She is widely recognized for her authoritative expertise in **Canada Good Clinical Practice (GCP) and has successfully led regulatory strategy, Clinical Trial Applications (CTA/IND/IMPD), and end-to-end clinical operations** for more than 38 Phase I–IV trials across North America, Europe, and Asia-Pacific. Her **extensive engagement with regulatory authorities, including Health Canada, the FDA, and the EMA**, positions her as a trusted authority in GCP compliance, inspection readiness, and clinical governance.

Dr. Kohli has played a pivotal role in securing regulatory approvals for vaccines, biologics, and biosimilars—including several high-impact and commercially significant products. She has held senior leadership positions, where **she has established and strengthened GxP-compliant quality systems, ensuring operational excellence and audit readiness across complex clinical programs**. Renowned for her ability to translate dense regulatory requirements into practical, execution-focused strategies, she is also an experienced educator who delivers highly engaging, insightdriven training to clinical and regulatory professionals worldwide.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - FOUNDATIONS OF ICH & GCP

- Evolution of ICH: Mission, Structure, Harmonization
- GCP Principles (E6 R2 and Emerging R3 Concepts)
- Relationship Between ICH, Health Canada, FDA, EMA

MODULE 2 - THE CANADIAN REGULATORY LANDSCAPE AND PARTICIPANT PROTECTION

- Canadian Regulatory Landscape:
  - Food and Drugs Act
  - Food and Drug Regulations (C.05)
  - Health Canada Guidance Documents
- TCPS2 Core Principles
- Vulnerable Populations
- Canadian-specific Considerations:
  - French Language Requirements (Quebec)
  - Indigenous Community Engagement

MODULE 3 - COMPLIANCE, QUALITY SYSTEMS & RISK MANAGEMENT

- Quality Management System (QMS) Expectations Under ICH E6
- Risk-based Quality Management (RBQM)
- Critical Data and Critical Processes
- CAPA Development and Effectiveness Checks
- Health Canada Inspection Trends and Common Findings
- Sponsor Oversight Expectations (Including Vendor Oversight)
- Documentation Practices (ALCOA+, Audit Trials, Data Integrity)

MODULE 4 - ROLES & RESPONSIBILITIES ACROSS THE TRIAL ECOSYSTEM – PART 1 SPONSOR, CRO RESPONSIBILITIES AND OVERSIGHT

- Sponsor Responsibilities (E6 + C.05)
- CRO Responsibilities and Documentation
- Governance-level Quality Expectations
- Oversight Evidence for Inspections

MODULE 5 - ROLES & RESPONSIBILITIES ACROSS THE TRIAL ECOSYSTEM – PART 2 INVESTIGATOR AND SITE RESPONSIBILITIES

- Investigator Responsibilities (Delegation, Supervision, Medical Oversight)
- Qualified Investigator (QI) Role in Canada
- Delegation Logs, Training Documentation, Oversight Evidence
- Site Infrastructure and Responsibilities

PROGRAM AGENDA

MODULE 6 - PROTOCOL DEVELOPMENT & STUDY DESIGN

- Protocol Structure (ICH E6 + E8 R1)
- Designing for Quality: Endpoints, Estimands, Safety Monitoring
- Feasibility and Operational Considerations
- Inclusion/Exclusion Criteria and Justification
- Statistical Considerations and SAP Alignment
- Protocol Deviations vs Violations
- Canadian Considerations:
  - QI Input
  - REB Expectations

MODULE 7 - CLINICAL TRIAL APPLICATIONS (CTA) IN CANADA

- CTA Structure (HC/SC 3011, Protocol, IB, Chemistry/Manufacturing)
- Health Canada Review Process and Timelines
- No Objection Letter (NOL) Process
- Amendments, Notifications, and Safety Reporting Obligations
- Differences Between CTA and US IND/EU CTA
- Common Deficiencies and How to Avoid Them
- Sponsor-facing Templates for CTA Readiness

MODULE 8 - INFORMED CONSENT PROCESS, ETHICS AND DOCUMENTATION

- REB Review and Approval Processes
- Consent Form Structure and Required Elements
- Ongoing Consent and Re-consent
- Documentation and Audit Expectations

MODULE 9 - ESSENTIAL DOCUMENTS & TRIAL MASTER FILE (TMF)

- ICH E6 Section 8 Essential Documents
- TMF Structure (Paper, Hybrid, eTMF)
- Health Canada Expectations for Document Retention
- QC/QA of TMF
- Site Regulatory Binder vs Sponsor TMF
- Inspection-ready Documentation Strategies
- Common TMF Gaps and How to Prevent Them

MODULE 10 - SAFETY REPORTING & PHARMACOVIGILANCE

- AE/SAE Definitions and Attribution

PROGRAM AGENDA

- SUSARs and Expedited Reporting
- Health Canada Division 5 Safety Reporting Requirements
- Investigator Responsibilities for Safety Oversight
- DSURs and Annual Reporting
- Safety Monitoring Committees (DMC/DSMB)
- Real-world Examples of Safety Non-compliance

MODULE 11 - MONITORING APPROACHES AND RBQM

- Centralized, On-site, and Hybrid Monitoring
- Risk-based Monitoring Aligned with R2/R3
- Monitoring Plan Development

MODULE 12 - STUDY CONDUCT, DEVIATIONS AND ISSUE MANAGEMENT

- Managing Deviations and Violations
- Identifying and Escalating Issues
- Documentation and Reporting
- Preventive Controls

MODULE 13 - AUDITING & INSPECTIONS

- Audit Planning and Execution (Aligned With Your QA Expertise)
- Vendor Audits and Oversight
- Health Canada Inspection Process
- Preparing for Sponsor, CRO, and Regulatory Inspections
- Responding to Findings (Root Cause, CAPA, Follow-up)

MODULE 14 - PROBATION, FIXED-TERM CONTRACTS & TEMPORARY EMPLOYMENT

- Data Flow Mapping and Data Lifecycle
- EDC, eCOA, eSource, and Validation Requirements
- Query Management and Data Cleaning
- Database Lock and Audit Trails
- Statistical Analysis Considerations
- CSR Development and Health Canada Expectations
- Close-out Visits, Archiving, and Retention

MODULE 15 - EXAM PREPARATION, STRATEGIES AND CONFIDENCE BUILDING

- Review of Key GCP Principles and Canadian Requirements
- Practice Questions and Scenario-based Reasoning
- Tips for Interpreting Regulatory Language
- How to Approach Case-based Exam Items

PROGRAM AGENDA

- Confidence-building Techniques for High-stakes Assessments

EXAMINATION

YOUR CHARTER DESIGNATION

CHARTERED

By the vested power in the Board of Governors of Chartered Institute of Professional Certifications, the Advisory Board, Faculty and Curriculum Committee, do hereby certify

Juliana Silva

Has Been Conferred the Designation of

Certified Canada Good Clinical Practice Manager™

CGCP™

Has satisfied all the examination and experience requirements, and is duly admitted and licensed to use this charter, board certificate, and membership credentials

And has committed to abide by the membership declaration of ethics, rules of professional conduct and continuing education requirements as a member of Chartered Institute of Professional Certifications

Chair of the Board

CGCP CERTIFIED CANADA GOOD CLINICAL PRACTICE MANAGER™

Director

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 successful completion of this program, you will be awarded the **Certified Canada Good Clinical Practice Manager (CGCP™)** designation, which can be added to your resume, CV, and professional credentials. This industry-recognized certification carries lifelong validity.

Globally recognized, this certification affirms your authority to lead ethically sound, regulatory-compliant clinical trials within the Canadian framework. It validates your ability to apply ICH GCP principles, navigate Health Canada requirements, oversee trial stakeholders, and ensure participant safety and data integrity across the clinical trial lifecycle. Developed by the **Chartered Institute of Professional Certifications**, this program is independently accredited by the **CPD Certification Service**, reflecting the highest standards of continuing professional development.

ABOUT US

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

390 Certified and Fully Accredited Programs

87% Chartered Leaders Have Reported Career Promotions and Enhancements

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.

OUR FACULTY DIRECTORS

We Collaborate With Instructors From Renowned Institutions

HARVARD UNIVERSITY

Wharton University of Pennsylvania

Stanford University

UNIVERSITY OF MICHIGAN

LSE THE LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE

Columbia Business School

London Business School

CONTACT US TODAY

We Thank You for Your Ongoing Support of Our Programs

Singapore and Asia Pacific Enquiries

Email: advisor@charteredcertifications.com
Phone: +65 6716 9980
Address: Chartered Institute of Professional Certifications
1 Gateway Drive
#20-04 Westgate Tower
Singapore 608531

Australia and New Zealand Enquiries

Email: advisor@charteredcertifications.com
Phone: +61 3 9909 7310
Address: Chartered Institute of Professional Certifications
530 Little Collins Street, Level 1
Melbourne VIC 3000, Australia

UK, Europe and Middle East Enquiries

Email: advisor@charteredcertifications.com
Phone: +44 (020) 335 57898
Address: Chartered Institute of Professional Certifications
86-90 Paul Street
London, EC2A 4NE

USA Enquiries

Email: advisor@charteredcertifications.com
Phone: +1 888 745 8875
Address: Chartered Institute of Professional Certifications
99 Wall Street #3936
New York, NY 10005