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HEALTH CANADA MEDICAL PRODUCTS REGULATIONS & COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

Health Canada's medical products regulations rank among the most complex in the world, spanning multiple directorates and over **2,500 pages of legislation, regulations, and guidelines** that set exacting requirements for **drugs, medical devices, biologics, and clinical trials**. Mastering this intricate framework is essential, because Health Canada enforces its compliance standards without leniency, issuing an estimated 1,800 enforcement actions and fines every year against organizations that fall short.

This certified program moves beyond regulatory awareness into the practical controls and decisions that secure compliant market access. You will learn to navigate **UPHN and Special Access Program pathways**, importer and distributor responsibilities, and **QMS, GMP, and MDSAP requirements**. These capabilities will equip you to strengthen quality systems and close compliance gaps long before they disrupt market access.

Building on this foundation, you will examine clinical trial application, investigational testing authorization, and clinical-evidence requirements, enabling you to support stronger submissions and better-informed product-development decisions. You will also build real capability in bilingual labeling, promotional compliance, and post-market obligations. Through practical case studies, you will compare classification approaches across **Health Canada, FDA, and EU frameworks**, assess significant changes affecting higher-risk devices, and prepare decisively for Health Canada inspections. The result: your organization identifies regulatory issues earlier, responds to findings with confidence, and makes faster, more consistent, and more defensible regulatory decisions.

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PROGRAM OVERVIEW

Finally, you will explore how **global harmonization and upcoming regulatory changes** reshape Canadian market access and broader commercialization strategies. By understanding how Health Canada requirements interact with other regulatory frameworks, you will anticipate change rather than react to it, assess cross-market implications with clarity, and drive more coordinated regulatory planning, strengthening global readiness while raising the consistency and quality of regulatory decision-making across your organization.

Upon successful completion, you will attain the **Certification in Health Canada Medical Products Regulations & Compliance**. This lifelong credential demonstrates your command of pre-market requirements, market authorization, lifecycle compliance, and post-market vigilance, and positions you as a trusted authority within Canada's regulated medical-products sector.

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KEY SKILLS YOU WILL GAIN

From This Program

HEALTH CANADA REGULATORY FRAMEWORK
MEDICAL PRODUCT CATEGORY DIFFERENTIATION
RISK-BASED PRODUCT CLASSIFICATION
MEDICAL DEVICE CLASS I–IV ASSESSMENT

CROSS-JURISDICTIONAL CLASSIFICATION ANALYSIS
MEDICAL DEVICE LICENCE (MDL) REQUIREMENTS
MEDICAL DEVICE ESTABLISHMENT LICENCE (MDEL) REQUIREMENTS

LICENSING PREREQUISITE ASSESSMENT
REGULATORY SUBMISSION STRATEGY
REGULATORY QUERY RESPONSE
POST-LICENCE CHANGE MANAGEMENT

SIGNIFICANT CHANGE ASSESSMENT
DRUG & BIOLOGIC REGULATORY PATHWAYS
NATURAL HEALTH PRODUCT COMPLIANCE
MARKET AUTHORIZATION STRATEGY
SOFTWARE & AI MEDICAL DEVICE REGULATION

URGENT PUBLIC HEALTH NEED (UPHN) ACCESS
SPECIAL ACCESS PROGRAM (SAP) NAVIGATION

YOUR FACULTY DIRECTOR

Sujata Ghatpande, PMP, PMI-ACP

An Accomplished Quality & Regulatory Professional

Sujata Ghatpande, PMP, PMI-ACP is an accomplished quality and regulatory professional with **more than 15 years of medical-device industry experience**, specializing in software and AI-enabled medical devices. Her expertise spans regulatory strategy, quality management, product development, and commercialization, guiding startups and fast-growing MedTech companies through Canadian and international requirements. As a consultant and fractional leader, she converts complex regulatory expectations into practical, scalable compliance strategies that clear the path to safe and effective market entry.

Her credentials include hands-on experience with **ISO 13485:2016, MDSAP readiness, EU MDR, regulatory clearances, and quality-system audits**. Her professional record also includes **regulatory consulting on an FDA-cleared Class II AI-enabled radiological device**, reinforcing her authority on emerging medical technologies. She gives participants a pragmatic, real-world perspective on **regulatory compliance, quality systems, and medical product commercialization**.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - OVERVIEW OF CANADIAN MEDICAL PRODUCTS

- Types of Medical Products
- Governing Regulations for Each Type of Medical Product
- Similarities and Differences in the Governing Regulations with Other Major Regulators

MODULE 2 - CLASSIFICATION OF MEDICAL PRODUCTS AND REGULATORY PATHWAYS – RISK-BASED CLASSIFICATIONS

- Cross-category Product Classification & Software/AI Medical Devices
- Case Study: Risk-based Product Classification

MODULE 3 - MEDICAL DEVICE LICENSING

- What is MDL and MDEL? Pre-requisites for Licensing, Process and Timelines
- Preparing Submissions and Responding to Queries
- Significant Changes and Managing Changes to Products After License Approvals

MODULE 4 - DRUG, BIOLOGIC AND NATURAL HEALTH PRODUCT REGULATIONS

- Pharmaceuticals, Biologics, NHPs & Canadian Market Authorization
- Preparing Submissions and Responding to Queries
- Significant Changes and Managing Changes to Products After License Approvals

MODULE 5 - FAST-TRACKED CLEARANCES

- Fast-tracked Clearances – Urgent Public Health Need (UPHN) and Special Access Program (SAP)
- Process to Get UPHN and SAP Licenses

MODULE 6 - CANADIAN MEDICAL PRODUCT IMPORTERS AND DISTRIBUTORS

- How to Get an Importer/ Distributor?
- Obligations of Importers and Distributions

MODULE 7 - GOOD MANUFACTURING PRACTICES (GMP) REQUIREMENTS

- Quality Management Systems and Good Manufacturing Practices (GMP)
- MDSAP and Quality System Audits
- GMP Requirements and Audits

PROGRAM AGENDA

MODULE 8 - RUNNING CLINICAL TRIALS IN CANADA

- Clinical Trials & Investigational Testing Compliance
- Differences Based on Risk Classification of the Product

MODULE 9 - CANADIAN MEDICAL PRODUCT – LABELING AND MARKETING REQUIREMENTS

- Labeling, Marketing, Promotional Materials Compliance Requirements, Including Bilingual Requirements

MODULE 10 - POST-MARKET REQUIREMENTS

- Post-Market Surveillance, Vigilance & Product Safety
- Similarities and Differences in Reporting Requirements Across Types of Medical Products

MODULE 11 - HEALTH CANADA INSPECTIONS AND AUDITS

- How to Prepare for and Respond to Audits
- Inspections and Audits for Foreign Manufacturers, Importers, and Distributors

MODULE 12 - WHAT'S NEXT FOR CANADIAN REGULATIONS?

- How is Health Canada Integrating With Other Regulatory Frameworks?
- How Does Having a Health Canada Market Authorization Benefit a Manufacturer Globally?
- Upcoming Changes

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 successful completion of this program, you will be awarded the **Certification in Health Canada Medical Products Regulations & Compliance**, a **lifelong credential** you can carry on your resume, CV, and professional profile to demonstrate advanced capability in Canadian medical product regulation.

This certification proves your command of **Canadian medical product regulations, regulatory submissions, and compliance management**. Developed by the **Chartered Institute of Professional Certifications**, the program content has been independently accredited by **CPD Certification Service** as conforming to Continuing Professional Development principles.

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

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