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NEW ZEALAND MEDICINES LAW, PRESCRIBING REGULATIONS AND LEGAL COMPLIANCE

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By:**

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PROGRAM OVERVIEW

New Zealand's medicines regulatory framework grows more complex each year, demanding that healthcare professionals navigate detailed medicines legislation, strict controlled-drug requirements, and evolving Medsafe expectations. **With medication errors contributing to over 700 preventable deaths annually and compliance breaches carrying serious legal consequences, the cost of uncertainty is simply too high.** As regulatory expectations continue to evolve, a confident command of New Zealand medicines law is essential for ensuring compliant prescribing, effective medicines governance, and safer patient outcomes.

This certified program equips you with the practical expertise to confidently navigate New Zealand's medicines regulatory framework and prescribing obligations. You will build a strong command of **medicine classification requirements and prescribing authorities' standards aligned with New Zealand's key medicines legislation, including the Medicines Act 1981, Medicines Regulations 1984, and Medsafe's regulatory expectations.** By deepening your knowledge of these critical legal and regulatory requirements, you will be far better positioned to make informed prescribing decisions, drive organizational compliance, and minimize regulatory and professional risk.

Throughout the program, you will develop practical skills in prescribing governance, documentation compliance, and professional accountability. You will learn how to **manage controlled drugs in accordance with legal requirements, strengthen governance over high-risk medicines, and establish**

ACCREDITATIONS



4.8



4.6





PROGRAM OVERVIEW

more effective medicines management systems. The program also addresses **pharmacovigilance responsibilities, adverse reaction reporting, and medicines safety monitoring,** equipping you to advance patient safety outcomes and embed robust risk management practices across your organization.

A defining feature of this program is its strong focus on real-world application through case studies and regulatory scenarios. You will examine **real-world cases involving prescribing errors, controlled-drug compliance failures, and regulatory investigations.** Through these practical examples, you will gain a sharper understanding of how prescribing decisions are scrutinized by regulators and professional bodies. This insight will help you strengthen documentation practices, make more defensible prescribing decisions, and manage compliance risks with far greater confidence.

Upon successful completion, you will earn the **Certification in New Zealand Medicines Law and Prescribing Compliance.** This credential validates your expertise in applying New Zealand medicines legislation, navigating prescribing and compliance obligations, and managing legal and regulatory risks. Globally recognized and actively sought by employers, it demonstrates your authority to lead medicines governance, strengthen compliance systems, and uphold safe prescribing practices.

ACCREDITATIONS



4.8




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KEY SKILLS YOU WILL GAIN

From This Program



**NEW ZEALAND MEDICINES LEGISLATION
MEDICINES ACT 1981 COMPLIANCE
MEDICINES REGULATIONS 1984 APPLICATION
MEDSAFE REGULATORY REQUIREMENTS**

**MEDICINES CLASSIFICATION FRAMEWORKS
MEDICINES SCHEDULING REQUIREMENTS
REGULATORY APPROVAL PROCESSES
MARKET AUTHORIZATION PATHWAYS**

**PRESCRIBING COMPLIANCE MANAGEMENT
PROFESSIONAL ACCOUNTABILITY STANDARDS
CONTROLLED MEDICINES COMPLIANCE
HIGH RISK MEDICINES MANAGEMENT**

**STORAGE AND MONITORING REQUIREMENTS
OFF LABEL PRESCRIBING GOVERNANCE
INFORMED CONSENT PRACTICES
TELEHEALTH PRESCRIBING COMPLIANCE
DIGITAL HEALTH REGULATIONS**

**CLINICAL DOCUMENTATION STANDARDS
PHARMACOVIGILANCE SYSTEMS MANAGEMENT**

YOUR FACULTY DIRECTOR



Lina Lozano

Highly Experienced Medical Regulatory Affairs and Compliance Expert

Lina Lozano is a highly accomplished New Zealand-based Pharmacist, Regulatory Affairs Specialist, and Compliance Leader with extensive experience across medicines regulation, pharmaceutical compliance, and healthcare product governance. She brings **extensive expertise in New Zealand medicines legislation, pharmacovigilance, controlled medicines compliance, regulatory submissions, and medicines risk management.** Her work spans prescription medicines, over-the-counter medicines, medicinal cannabis, and global product registration across some of the world's most heavily regulated healthcare markets.

Lina has held regulatory and compliance leadership roles with leading organizations including Cannasouth Bioscience, Bayer, and AFT Pharmaceuticals, where she **managed regulatory registrations, licensing requirements, pharmacovigilance activities, and market authorization strategies.** She currently **advises organizations across New Zealand, APAC, Europe, the Americas, Africa, and the Middle East on medicines compliance, regulatory strategy, audit readiness, and legal risk management.**

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PROGRAM AGENDA



MODULE 1: INTRODUCTION TO NEW ZEALAND MEDICINES REGULATORY FRAMEWORK AND GOVERNANCE

- Overview of New Zealand medicines regulatory framework
- Role of Medsafe and key regulatory authorities
- Overview of Medicines Act and Medicines Regulations

MODULE 2: MEDICINES CLASSIFICATION, SCHEDULING, AND REGULATORY CONTROLS

- Classification and scheduling of medicines
- Prescription, OTC, and controlled drugs framework

MODULE 3: MEDICINES REGISTRATION, EVALUATION, AND MARKET AUTHORISATION PROCESSES

- Regulatory process for registering medicines in New Zealand
- Evaluation of quality, safety, and efficacy data
- Market authorisation and approval pathways

MODULE 4: PRESCRIBING RESPONSIBILITIES, PROFESSIONAL ACCOUNTABILITY, AND PATIENT SAFETY

- Legal responsibilities of prescribers
- Scope of practice and accountability
- Consent and patient safety obligations

MODULE 5: CONTROLLED DRUGS AND HIGH-RISK MEDICINES COMPLIANCE MANAGEMENT

- Controlled drugs compliance
- High-risk medicines management
- Storage, prescribing, and monitoring requirements

MODULE 6: OFF-LABEL PRESCRIBING, LEGAL OBLIGATIONS, AND RISK MITIGATION

- Off-label prescribing and regulatory expectations
- Clinical decision-making within prescribing authority and scope
- Legal liability, documentation requirements, and risk mitigation strategies

PROGRAM AGENDA



MODULE 7: TELEHEALTH PRESCRIBING, DIGITAL HEALTH COMPLIANCE, AND VIRTUAL CARE REGULATIONS

- Telehealth prescribing within New Zealand's regulatory framework
- Digital health and remote consultation compliance requirements
- Patient assessment standards, documentation, and clinical recordkeeping in virtual care

MODULE 8: PHARMACOVIGILANCE, ADVERSE DRUG REACTION REPORTING, AND POST-MARKET SURVEILLANCE

- Pharmacovigilance and adverse drug reaction reporting
- Post-market safety monitoring requirements
- Regulatory reporting obligations

MODULE 9: REGULATORY INVESTIGATIONS, COMPLIANCE BREACHES, AND ENFORCEMENT ACTIONS

- Regulatory investigations and compliance breaches
- Complaints handling and disciplinary processes

- Legal exposure and enforcement mechanisms

MODULE 10: ORGANISATIONAL MEDICINES COMPLIANCE AND LEGAL RISK MANAGEMENT SYSTEMS

- Medicines compliance in healthcare organisations
- Legal risk management strategies
- Building robust compliance systems

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 New Zealand Medicines Law and Prescribing Compliance**, ready to be added to your resume, CV, and professional credentials. This certification is industry-recognized and carries lifelong validity.

Globally recognized and in high demand, this certification elevates your professional profile and demonstrates your expertise in navigating medicines legislation, prescribing obligations, and regulatory compliance requirements. It validates your capability to lead medicines governance, safeguard patient safety, and embed effective compliance frameworks across healthcare and pharmaceutical environments. This program is developed by the **Chartered Institute of Professional Certifications**, and its content has been certified by **CPD Certification Service** as adhering to the highest standards of continuing professional principles.

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of Our Programs

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