CHARTERED
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AUSTRALIA CLINICAL TRIAL TGA REGULATIONS AND GCP COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

Australia's status as a prime location for clinical trials is highlighted by its conduct of over 1,000 trials annually, marking its significant contribution to global research and development. The nation's commitment is further demonstrated by its adherence to Good Clinical Practice (GCP) standards, with over 95% compliance. This strict observance not only **safeguards participant safety, with serious adverse events occurring in less than 0.5% of cases, but also bolsters the integrity and international standing of its research findings**. Mastery of Australia's regulatory landscape and stringent GCP guidelines is essential for navigating its complex clinical trial environment.

This certified program is designed to equip you with the essential knowledge and skills needed to effectively address the practical challenges of compliance in the clinical trial landscape. You will gain knowledge on a broad spectrum of critical topics, including an in-depth exploration of the **Therapeutic Goods Administration (TGA) regulations, Good Clinical Practice (GCP) guidelines, ethical considerations, safety reporting, data management, and quality assurance**. Participants will also gain a thorough understanding of the **latest regulatory requirements and best practices in clinical trial compliance**.

Throughout the program, you will delve into the intricacies of the **TGA's Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes**, gaining insights into the application process, documentation requirements, and timelines. You will also learn about the roles and responsibilities of **key stakeholders, such as sponsors, investigators, Human Research Ethics Committees (HRECs), and institutional review boards (IRBs)**. Additionally, this program will cover the principles of GCP, including informed consent, **participant safety, data integrity, and investigator responsibilities**.

ACCREDITATIONS

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PROGRAM OVERVIEW

Throughout the program, participants will acquire practical skills in **developing robust clinical trial protocols, managing essential documents, and implementing effective quality management systems**. The program will also address the importance of pharmacovigilance and safety reporting, providing guidance on identifying, assessing, and reporting adverse events and serious adverse events. Furthermore, you will learn about **data management and statistical considerations in clinical trials**, ensuring the integrity and reliability of trial results.

Upon successfully completing the program, you will attain the highly respected **Certification in Australia Clinical Trial Regulations and Compliance**. This certification will serve as a testament to your expertise in navigating the complex landscape of clinical trial regulations and their commitment to upholding the highest standards of compliance. This industry-recognized certification will enhance participants' professional credentials and demonstrate their proficiency in **designing, conducting, and managing clinical trials in accordance with TGA regulations and GCP guidelines**.

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KEY SKILLS YOU WILL GAIN

From This Program

AUSTRALIA CLINICAL REGULATORY COMPLIANCE
TGA REGULATION
GOOD CLINICAL PRACTICE COMPLIANCE
CLINICAL TRIAL APPLICATIONS

INFORMED CONSENT
CLINICAL TRIALS ADMINISTRATION
PHARMACOVIGILANCE
RISK ASSESSMENT

ETHICAL RESEARCH
GDPR COMPLIANCE
CLINICAL TRIAL AUDITING
CLINICAL TRIAL DESIGN

CLINICAL INVESTIGATIONS
SAFETY REPORTING
CLINICAL TRIAL INSURANCE
CLINICAL QUALITY ASSURANCE (CQA)
CLINICAL TRIAL REPORTING

AU CLINICAL TRIALS LEGISLATION
CLINICAL TRIALS AUTHORIZATION

YOUR FACULTY DIRECTOR

Melinda Borrelli

Renowned Clinical Research and GCP Compliance Expert

Melinda Borrelli is a distinguished Clinical Research Professional with over 20 years of expertise in Australia's biotechnology industry. Her career encompasses a variety of roles that have cultivated a deep understanding of clinical research complexities, making her an expert mentor in the field.

Proficient in project management, **Melinda has demonstrated her expertise through her proficiency in Electronic Data Capture (EDC), Good Clinical Practice (GCP), Clinical Trials, and CRO management**. Now a **certified vocational Trainer and Assessor**, Melinda has transitioned to educating others, drawing on her extensive experience to guide peers through their professional development. She is a **compelling presenter, known for engaging and enlightening audiences at both local and international conferences**. Melinda Borrelli continues to be a catalyst for growth and excellence in the clinical research field, nurturing new talent and enhancing professional standards through her dynamic leadership and commitment to advancing clinical research practices.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - FOUNDATIONS OF CLINICAL TRIALS: INTRODUCTION AND REGULATORY EVOLUTION

- Lesson 1 - Introductions and Course Overview
- Lesson 2 - Purpose of Regulatory & GCP Requirements
- Lesson 3 - Evolution of Regulatory & GCP Requirements
- Lesson 4 - Global Adoption of ICH/GCP

MODULE 2 - NAVIGATING TGA REGULATIONS

- Lesson 1 - In-Depth Look at Therapeutic Goods Authority (TGA)
- Lesson 2 - NHMRC National Statement
- Lesson 3 - TGA & NHMRC Guidance
- Lesson 4 - Facilitated Online Review of TGA Website and Resources

MODULE 3 - AUSTRALIAN CLINICAL TRIAL APPLICATION AND APPROVAL PROCESS

- Lesson 1 - Overview of Australian Regulatory Submission and Approval Process
- Lesson 2 - CTN/CTA Applications
- Lesson 3 - Sourcing Information to Complete the Application e-form

MODULE 4 - UNDERSTANDING CTN/CTA: ACKNOWLEDGMENT VS APPROVAL

- Lesson 1 - No Such Thing as CTN/CTA Approval
- Lesson 2 - What Does CTN/CTA Acknowledgment Mean?

MODULE 5 - APPLYING GCP STANDARDS: ROLES, RESPONSIBILITIES, AND DOCUMENTATION

- Lesson 1 - Applying Regulatory & GCP Requirements in Practice
- Lesson 2 - Roles & Responsibilities
- Lesson 3 -What are the Essential Documents?

MODULE 6 - ETHICAL FOUNDATIONS IN AUSTRALIAN CLINICAL RESEARCH

- Lesson 1 - Australian Ethics Submission & Approval Process
- Lesson 2 - Research Governance Office
- Lesson 3 - Sub Committee Requirements

PROGRAM AGENDA

MODULE 7 - QUALITY AND INTEGRITY IN CLINICAL TRIALS

- Lesson 1 - Quality Management
- Lesson 2 - Fraud & Misconduct
- Lesson 3 - Role of Audits
- Lesson 4 - Red Flags

MODULE 8 - CLINICAL TRIAL SAFETY MANAGEMENT: REPORTING, PLANNING, AND COMPLIANCE

- Lesson 1 - Safety Reporting Overview
- Lesson 2 - SAEs & SUSARs
- Lesson 3 - Progress Reports
- Lesson 4 - Mandatory Reporting Timelines

MODULE 9 - ENSURING COMPLIANCE THROUGH EFFECTIVE CLINICAL TRIAL MONITORING

- Lesson 1 - Monitoring Clinical Trials: Documentation
- Lesson 2 - Monitoring Clinical Trials: Electronic Medical Records
- Lesson 3 - Monitoring Clinical Trials: Informed Consent
- Lesson 4 - Monitoring Clinical Trials: Non-Compliance

MODULE 10 - NAVIGATING COMPLEX REGULATIONS

- Lesson 1 - Other Regulatory Requirements: Investigational Product Import & Export
- Lesson 2 - Other Regulatory Requirements: Biological Investigational Product
- Lesson 3 - Other Regulatory Requirements: Investigational Product Labels
- Lesson 4 - Other Regulatory Requirements: Lab or Diagnostic Kits
- Lesson 5 - Clinical Trial Registration

YOUR CHARTER DESIGNATION

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

Upon successfully attending this program, you will be awarded with the **Certification in Australia Clinical Trial Regulations and Compliance** that can be used in your resume, CV and other professional credentials. This certification is industry-recognized with lifelong validity.

Globally demanded and recognized, this certification will amplify your professional qualifications and demonstrate your expertise in navigating the intricacies involved in Australia's clinical trials TGA regulations and GCP compliance. Developed by **Chartered Institute of Professional Certifications**, the content of this program has been independently accredited by **CPD Certification Service** as adhering to the highest standards of continuing professional 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 program are fully accredited programs. The professional charter 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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We Thank You for Your Ongoing Support of Our Programs

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