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AUSTRALIA THERAPEUTIC GOODS ADMINISTRATION (TGA) REGULATIONS AND COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

Australia's TGA regulations encompass a broad range of products, from pharmaceuticals to medical devices and complementary medicines. **The complexity of these regulations leads to lengthy and intricate compliance processes.** For instance, compliance with the TGA's medical device regulations requires meeting around 50 different standards, creating a complex regulatory environment that over 60% of small to medium-sized enterprises find difficult to navigate.

This certified training program will provide you with an in-depth, technically robust understanding of Australia's TGA regulations, equipping you with the critical knowledge and practical tools necessary to achieve and sustain **full regulatory compliance for therapeutic products, clinical trials, and research activities**. Designed for professional leaders navigating Australia's complex pharmaceutical, biotechnology, and medical device landscape, this program provides a structured approach to mastering the intricate requirements set by the TGA. You will gain a detailed understanding of critical compliance areas, including **Good Manufacturing Practice (GMP) requirements, product registration pathways, clinical evidence standards, pharmacovigilance obligations, and regulatory reporting mechanisms.**

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PROGRAM OVERVIEW

Throughout the program, you will also explore the complexities of **TGA approvals, including pre-market assessment, regulatory submissions, and conformity assessment requirements for medical devices, prescription medicines, biologics, and complementary and alternative therapies**. You will develop the skills to classify therapeutic goods correctly, interpret **regulatory expectations for clinical trial authorization, and ensure compliance with stringent safety, quality, and efficacy standards**. This program will also cover critical **post-market surveillance obligations, including adverse event monitoring, real-world evidence collection, and regulatory audits**, ensuring you remain aligned with evolving TGA enforcement priorities.

Upon successful completion of the program, you will attain the **Certification in Australia Therapeutic Goods Administration (TGA) Regulations and Compliance**, enhancing your professional credentials and demonstrating your expertise in navigating TGA challenges, ensuring compliance, reducing risks, and strengthening your organization's regulatory strategy for safe and effective healthcare products. Globally demanded and recognized, the certification holds lifelong validity and will underscore your expertise and amplify your professional credentials in the vital area of medical and healthcare regulations.

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KEY SKILLS YOU WILL GAIN

From This Program

TGA REGULATORY COMPLIANCE
ARTG REGISTRATION
GMP AND GCP IMPLEMENTATION
THERAPEUTIC GOODS ACT 1989

PHARMACOVIGILANCE AND RISK MANAGEMENT
MEDICAL DEVICE CLASSIFICATION
REGULATORY AUDIT
REGULATORY PATHWAY SELECTION

INSPECTION PREPAREDNESS
GOOD CLINICAL PRACTICE (GCP) COMPLIANCE
ADVERSE EVENT REPORTING
POST-MARKET SURVEILLANCE

TGA REGULATORY FRAMEWORK
PRODUCT LIFE-CYCLE MANAGEMENT
REGULATORY SUBMISSION PREPARATION TGA
CLINICAL TRIAL NOTIFICATION (CTN)
CLINICAL TRIAL EXEMPTION (CTX) SCHEMES

GMP INSPECTION
RECALL MANAGEMENT

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 - INTRODUCTION TO TGA & AUSTRALIAN REGULATORY FRAMEWORK

- TGA's Role in Healthcare Regulation
- Key Legislation: Therapeutic Goods Act 1989 & Regulations
- Global Regulatory Comparison: TGA vs. FDA, EMA, MHRA

MODULE 2 - PRODUCT CLASSIFICATION

- Risk-Based Product Classification - Medicines (Prescription, OTC, Complementary), Medical Devices & Biologicals & IVDs
- TGA Online Resources Review

MODULE 3 - GOOD MANUFACTURING PRACTICE

- TGA GMP Requirements
- GMP Compliance & Global Standards
- GMP Inspections & CAPA Strategies
- GMP Case Study & Quiz

MODULE 4 - CLINICAL TRIALS & RESEARCH COMPLIANCE

- Clinical Trial Submission & Approval - (CTN vs. CTX Schemes)
- Regulatory Responsibilities - (Sponsors, CRAs, Clinical Trial Managers & Medical Affairs)
- GCP Compliance
- Reporting Obligations

MODULE 5 - REGULATORY PATHWAYS FOR MARKET ENTRY

- Market Authorization & Application Pathways
- Successful Submission Preparation (CTD & Dossier)
- TGA Fees & Assessment Timelines
- ARTG Registration Process
- Case Study

MODULE 6 - POST-MARKET OBLIGATIONS & RISK MANAGEMENT

- Post-Approval & Lifecycle Management
- Pharmacovigilance & Device Vigilance
- Safety Reporting (AE/SAE, PSURs, RMPs)

MODULE 7 - REGULATORY COMPLIANCE & AUDITS

- TGA Audits & Sponsor Responsibilities
- Common Audit Findings & Corrective Actions
- TGA Audits & Inspections: Process, Deficiencies & Corrective Actions
- Case Studies: GMP Non-Compliance, Clinical Trial Breaches & Labeling Issues

PROGRAM AGENDA

MODULE 8 - POST-MARKET SURVEILLANCE & PHARMACOVIGILANCE

- Adverse Event Reporting
- TGA Recalls and Risk Management
- Case Study

MODULE 9 - CASE STUDIES & GROUP DISCUSSIONS

- Case Study 1: Regulatory Affairs (Registration Failures, Post-Market Issues)
- Case Study 2: Compliance (Labeling, Advertising, Off-Label Use, GMP Violations)
- Case Study 3: Medical Devices (Post-Market Monitoring, Complaints, Recalls)
- Case Study 4: Clinical Research (Trial Misconduct, GCP Non-Compliance)

MODULE 10 - FINAL Q&A

- Participant Assessment (Quiz or Case Study)
- Certification & Closing Remarks

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 attending this program, you will be awarded with the **Certification in Australia Therapeutic Goods Administration (TGA) 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 demonstrates your expertise in navigating Australia's TGA regulations, enabling you to develop effective compliance strategies, manage regulatory risks, and ensure the safety and efficacy of therapeutic goods in the Australian market. By earning this certification, you will be recognized as a subject matter expert in TGA regulations compliance and will be well-equipped to take on leadership roles in regulatory affairs, quality assurance, and compliance management. This program is developed by **Chartered Institute of Professional Certifications** and the content of this program has been certified by **CPD Certification Service** as conforming to continuing professional principals.

ABOUT US

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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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London Business School

CONTACT US TODAY

We Thank You for Your Ongoing Support of Our Programs

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