

**CHARTERED**   
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

# 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.**

## ACCREDITATIONS



4.8



4.6





# 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.

## ACCREDITATIONS



4.8



4.6



# 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



Goldman Sachs



SAMSUNG



ExxonMobil



BURBERRY



Citi



IKEA



VOLVO



HYUNDAI



Pfizer

Life is our life's work



Nestlé

# 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

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.

**CHARTERED**   
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

# OUR FACULTY DIRECTORS

We Collaborate With  
Instructors From  
Renowned Institutions



**HARVARD**  
UNIVERSITY



**Wharton**  
UNIVERSITY of PENNSYLVANIA



**Stanford University**



**UNIVERSITY OF MICHIGAN**



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