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CERTIFIED GOOD CLINICAL PRACTICE MANAGER™

CGCP ™

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

CGCP™
CERTIFIED GOOD CLINICAL PRACTICE MANAGER™

PROGRAM OVERVIEW

According to a recent study by the FDA, approximately **34% of clinical investigator inspection findings between 2020 - 2024 involved GCP violations such as inadequate record keeping, protocol deviations, or informed consent issues.** These violations not only compromise data integrity but also pose significant risks to participant safety and regulatory approval. Strengthening GCP compliance frameworks is therefore essential to ensure ethical conduct, reliable outcomes, and successful trial execution.

This certified program is designed to equip clinical research professionals with the knowledge, tools, and strategies needed to proactively identify and address compliance risks, implement robust quality systems, and uphold the highest standards of ethical and regulatory conduct across all phases of clinical trials. Throughout the program, you will explore a broad range of core clinical research management topics such as **strategic quality planning, advanced risk-based monitoring approaches, and rigorous inspection readiness preparation.** This program will help you effectively oversee and **optimize GCP compliance across any clinical research organization.** You will emerge with the ability to develop comprehensive quality management systems, anticipate regulatory challenges, and influence trial strategy directly.

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PROGRAM OVERVIEW

Additionally, the program will show you specialized GCP management techniques such as **optimizing essential document systems with validated electronic solutions, managing cross-border regulatory variations, and understanding the intricacies of site oversight and clinical monitoring.** You will also gain skills in **protocol deviation management and investigational product accountability, alongside learning how to navigate inspection processes and regulatory interactions effectively.** Ethical considerations and subject protection are also pivotal components of this program, preparing you to implement and evaluate clinical trial strategies that align with both scientific objectives and international ethical standards. By the end of the program, you will be equipped to assume high-level clinical research responsibilities, driving compliance strategy and fostering organizational excellence with confidence and precision.

Upon completing the program and passing the Chartered exam, you will attain the **Certified Good Clinical Practice Manager (CGCP™)** designation that will demonstrate your expertise in overseeing ethical, high-quality, and inspection-ready clinical trials. This CGCP™ credential will distinguish you as a trusted leader in driving compliant and high-performing clinical research internationally.

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KEY SKILLS YOU WILL GAIN

From This Program

GCP REGULATORY INTERPRETATION
RESEARCH GOVERNANCE COMPLIANCE
ETHICS VS GOVERNANCE DIFFERENTIATION
SITE APPROVAL OPTIMIZATION

ICH GCP GUIDELINES
INVESTIGATOR OVERSIGHT
DELEGATION MANAGEMENT
AUDIT READINESS PLANNING

SPONSOR ROLE CLARIFICATION
THERAPEUTIC GOODS COMPLIANCE
INVESTIGATIONAL PRODUCT (IP) MANAGEMENT
HOME-USE IP PROTOCOLS

CLINICAL TRIAL BUDGETING
CONFLICT OF INTEREST MANAGEMENT
STATISTICAL TRIAL DESIGN
RANDOMISATION IMPLEMENTATION
UNBLINDING PROCEDURES

DATA GOVERNANCE STRATEGIES
ESSENTIAL DOCUMENT CONTROL

YOUR FACULTY DIRECTOR

Prof. Nikolajs Zeps

Distinguished National Leader in Clinical Research, Health Ethics, and Trial Innovation

Prof. Nikolajs Zeps is a distinguished leader in clinical research and Good Clinical Practice (GCP) compliance, recognized nationally for his exceptional contributions to advancing clinical and translational research. He currently serves as **Director of Operations for the Cancer Research Program and Professor of Practice in the Department of Chronic Disease and Ageing at Monash University's School of Public Health and Preventive Medicine.** With an extensive executive background, Prof. Zeps previously held the position of Director of Research at Northern Health and has served in senior roles at St John of God HealthCare and Epworth HealthCare. He is also the Clinical Research Lead for Monash Partners and an Adjunct Professor at the Eastern Health Clinical School, Monash University.

Prof. Zeps has been instrumental in advancing clinical research capacity and Good Clinical Practice (GCP) compliance internationally. As a **founding Director and Board Member of the Australian Clinical Trials Alliance (ACTA)**, he has led national initiatives such as rapid trial start-up and teletrials programs. He **co-authored the Australian Clinical Trials Handbook for the TGA and received the NHMRC Ethics Prize** for his outstanding contributions to human research ethics. Prof. Zeps **chairs the PC4 Advisory Committee and drives national efforts to improve clinical trial accessibility and engagement through the VCCC Alliance's clinical trial participation workstream.**

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - GCP FOUNDATIONS AND THE GLOBAL REGULATORY LANDSCAPE

- Overview of the regulatory environment - Why do we need a GCP? The role of the regulatory agencies for clinical trials.
- What are the principles of GCP?
- How does GCP overlap with other regulatory requirements?

MODULE 2 - RESEARCH GOVERNANCE VS ETHICS: SITE APPROVAL AND GCP ALIGNMENT

- What is Research Governance and how does it relate to GCP?
- How do investigators and sponsors use GCP to obtain site approval?
- What are the core differences between ethical and research governance requirements?

MODULE 3 - INVESTIGATOR RESPONSIBILITIES AND GCP COMPLIANCE

- Investigator responsibilities for clinical trials.
- What can and cannot be delegated?
- How to demonstrate compliance with GCP?

MODULE 4 - SPONSOR RESPONSIBILITIES AND REGULATORY EXPECTATIONS

- What are sponsor responsibilities?
- How do these responsibilities differ to those of investigators?
- What are the responsibilities of a trial sponsor where they are not the manufacturer, importer or distributor of a therapeutic good?

MODULE 5 - INVESTIGATIONAL PRODUCT MANAGEMENT IN CLINICAL TRIALS

- Investigational product.
- Supply, storage and handling.
- Roles of sponsors vs investigators.
- Use of IP at site and at home.

MODULE 6 - TRIAL DESIGN INTEGRITY: RANDOMISATION AND UNBLINDING

- Statistical design - Types of trials.
- Randomisation procedures and unblinding.

MODULE 7 - DATA GOVERNANCE AND ESSENTIAL DOCUMENTATION STANDARDS

- Data governance.
- Data and records (Including essential records - Appendix C).
- Reporting outcomes.

PROGRAM AGENDA

MODUE 8 - PARTICIPANT SAFETY, REPORTING PATHWAYS, AND REGULATORY OVERSIGHT

- Managing the safety of participants.
- How are safety events reported?
- What is the role of the investigator, sponsor and DSMB?
- Communication with regulator, sites and ethics committees.
- Monitoring and inspections.

MODULE 9 - FINANCIAL MANAGEMENT AND CONFLICT OF INTEREST IN CLINICAL TRIALS

- Financial consideration.
- Budgets - How are they devised and what can be included?
- Managing conflicts of interest.

MODULE 10 - IMPLEMENTING QUALITY AND RISK MANAGEMENT IN CLINICAL TRIALS

- Quality management.
- Risk management.
- How to identify, evaluate and manage risks?
- Risk reporting.
- What is the role of quality assurance and quality control in risk management?

MODULE 11 - POST-TRIAL RESPONSIBILITIES AND PARTICIPANT CONTINUITY

- Post trial obligations and reporting.
- Managing participants post trial completion.

MODULE 12 - GCP IN ACTION: CASE REVIEWS AND ADAPTIVE TRIAL DESIGN

- Review of topics and discussion of real world applications.
- Discussion of different trial designs and how this is relevant to GCP.

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 **Certified Good Clinical Practice Manager (CGCP™)** designation. that can be used in your resume, CV and other professional credentials. This certification is industry-recognized with lifelong validity.

Globally recognized, this certification affirms your expertise in leading ethically sound, regulatory-compliant clinical trials in Australia and across the APAC region. It demonstrates your ability to apply GCP principles within complex governance frameworks, oversee stakeholder responsibilities, and ensure participant safety and data integrity across diverse trial settings. 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

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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

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We Thank You for Your Ongoing Support of Our Programs

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