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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

Dr. Jennifer Lai

Distinguished Clinical Research & Operations Expert

Dr. Jennifer Lai is a seasoned clinical research expert with over 25 years of global experience in clinical trial operations, clinical data management, and GCP compliance. She has **held leadership positions across the clinical research spectrum, from Clinical Research Associate to Vice President of Clinical Operations, giving her a comprehensive and practical command of Good Clinical Practice across all trial phases.**

Currently serving as Head of Clinical Operations at Hillhurst Biopharmaceuticals, Dr. Lai also consults on clinical operations strategy, offering real-world insights into GCP implementation, trial oversight, and regulatory preparedness. She has **successfully led multinational clinical operations teams, ensured consistent GCP adherence across complex global trials**, and developed training programs for research sites and clinical staff.

Her therapeutic expertise spans oncology, hematology, gastroenterology, neurology, ophthalmology, dermatology, and infectious diseases. Dr. Lai holds a **Certified Clinical Research Associate (CCRA) credential and an Advanced International Pharmacovigilance and Argus Safety Certification (APVASC)**. A published author, she contributed to peer-reviewed research on start-up delays in global trials and completed a postdoctoral fellowship in Clinical Research Ethics at the Medical University of South Carolina.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1: INTRODUCTION TO GOOD CLINICAL PRACTICE (GCP)

- Overview: Introduction to Good Clinical Practice (GCP)
- Lesson 1: What is GCP and Why is it Important
- Lesson 2: Historical and Regulatory Context of GCP
- Lesson 3: Core Principles of GCP

MODULE 2: GCP REGULATORY FRAMEWORK AND ETHICS IN CLINICAL RESEARCH

- Overview: GCP Regulatory Framework and Ethics in Clinical Research
- Lesson 4: Overview of GCP Framework
- Lesson 5: Declaration of Helsinki, ICH Guidelines and FDA, EMA Regulations
- Lesson 6: Informed Consent

MODULE 3: CLINICAL TRIAL DESIGN AND PROTOCOL DEVELOPMENT

- Overview: Clinical Trial Design and Protocol Development
- Lesson 7: Types of Clinical Trials (Phase I-IV)
- Lesson 8: Protocol Structure and Key Components
- Lesson 9: Eligibility Criteria and Study Endpoints

MODULE 4: OBSTACLES TO STUDY START-UP

- Overview: Obstacles to Study Start-Up
- Lesson 10: Site Feasibility and Selection
- Lesson 11: Delays in Ethics and Regulatory approvals
- Lesson 12: Budgeting and Contract Negotiations

MODULE 5: KEY STAKEHOLDER RESPONSIBILITIES (INVESTIGATOR, SPONSOR, IRB AND CRA)

- Overview: Key Stakeholder Responsibilities (Investigator, Sponsor, IRB and CRA)
- Lesson 13: Investigators
- Lesson 14: Sponsors & IRBs
- Lesson 15: Monitor (CRA)

MODULE 6: DOCUMENTATION AND RECORD MANAGEMENT

- Overview: Documentation and Record Management
- Lesson 16: Essential Documents (ICH GCP E6 Section 8)
- Lesson 17: TMF & ISF Management
- Lesson 18: Archiving & Audit Readiness

PROGRAM AGENDA

MODULE 7: MONITORING & QUALITY ASSURANCE

- Overview: Monitoring & Quality Assurance
- Lesson 19: Definitions
- Lesson 20: RBM Framework
- Lesson 21: Quality Assurance in Clinical Trials

MODULE 8: DATA MANAGEMENT AND BIOSTATISTICS

- Overview: Data Management and Biostatistics
- Lesson 22: Data Integrity
- Lesson 23: Clinical Data Management Lifecycle
- Lesson 24: Biostatistics and Analysis

MODULE 9: POST-TRIAL OBLIGATIONS AND REPORTING

- Overview: Post-Trial Obligations and Reporting
- Lesson 25: Clinical Study Report
- Lesson 26: Post Trial Access
- Lesson 27: Archiving and Record Retention

MODULE 10: EMERGING TRENDS AND FUTURE DIRECTIONS

- Overview: Emerging Trends and Future Directions
- Lesson 28: Decentralized Clinical Trials (DCTs)
- Lesson 29: Use of AI and Digital Health Tools
- Lesson 30: Regulatory Changes

EXAMINATION

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

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We Thank You for Your Ongoing Support of Our Programs

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