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CERTIFIED EU 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 recent data, **approximately 36% of inspected clinical trials in the EU between 2020 and 2024 exhibited GCP violations**, primarily related to inadequate documentation, protocol deviations, and failures in informed consent processes. These **breaches led to study suspensions and increased regulatory scrutiny, jeopardizing data accuracy as well as participant welfare**. Robust GCP compliance measures are therefore indispensable for upholding ethical standards, safeguarding patient safety, and securing the regulatory success of clinical research.

This certified program is designed to equip clinical research professionals, sponsors, and investigators with the knowledge, tools, and strategies required to manage Good Clinical Practice (GCP) compliance effectively under the **EU Clinical Trials Regulation (CTR 536/2014)** and **ICH E6(R3)**. You will gain the expertise to identify and address compliance risks proactively, implement robust quality systems, and uphold the highest standards of ethical and regulatory conduct across all phases of clinical research. Throughout the program, you will explore the full spectrum of GCP management, including **strategic quality planning, risk-based monitoring (RBQM), trial master file (TMF) management, CRO oversight**, and **inspection readiness** to ensure full alignment with EU and EMA expectations.

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PROGRAM OVERVIEW

Additionally, this program will guide you through specialized GCP management techniques such as ethical foundations of GCP, clinical research principles, and the integration of quality management into trial design. You will gain an in-depth understanding of **ethics committee roles, informed consent under GDPR**, and the protection of vulnerable populations through sound risk–benefit assessments. You will explore **investigator and sponsor responsibilities**, including site management, vendor qualification, staff training, and effective sponsor communication. You will focus on **protocol development**, emphasizing quality-by-design principles. You will learn to manage **Investigational Medicinal Products (IMPs)** in compliance with **GMP**, and maintain **data integrity** following **ALCOA+** standards. Key sessions on **pharmacovigilance** provide insight into AE, SAE, and SUSAR reporting, guiding you on **post-trial obligations**, transparency requirements in **CTIS**, and long-term data archiving.

By the end of the program, you will be fully prepared to lead ethically robust, inspection-ready, and regulation-compliant clinical trials that meet the highest standards.

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 in the EU.

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KEY SKILLS YOU WILL GAIN

From This Program

GCP COMPLIANCE
ICH E6(R3) IMPLEMENTATION
EU CTR 536/2014 COMPLIANCE
ETHICAL CLINICAL RESEARCH CONDUCT

RISK–BENEFIT ASSESSMENT
GDPR & PARTICIPANT PRIVACY
ETHICS COMMITTEE OVERSIGHT
INVESTIGATOR SITE MANAGEMENT

SPONSOR OVERSIGHT
CRO MANAGEMENT
TRIAL MASTER FILE (TMF) ADMINISTRATION
RISK-BASED QUALITY MANAGEMENT (RBQM)

QUALITY-BY-DESIGN (QBD) IN CLINICAL TRIALS
PROTOCOL DEVELOPMENT & REVIEW
STATISTICAL ANALYSIS PLANNING
DATA INTEGRITY (ALCOA+)
ELECTRONIC DATA CAPTURE (EDC/ECRF)

INVESTIGATIONAL MEDICINAL PRODUCT (IMP) MANAGEMENT

YOUR FACULTY DIRECTOR

Agnieszka Sokol

GCP Compliance Expert and Auditor | Quality Management Specialist

Dr. Agnieszka Sokol is a distinguished expert in **Good Clinical Practice (GCP) compliance, clinical quality management**, and **regulatory training**, with over **18 years of experience** in the pharmaceutical and biotechnology industries. She has held senior roles at **argenx, Samsung Bioepis, Covance (for MSD)**, and **Roche Poland**, where she led global initiatives in audit and inspection readiness, quality system development, and risk-based trial oversight.

As an **independent consultant**, Dr. Sokol advises pharmaceutical companies, biotech firms, and CROs on **GCP auditing, inspection facilitation**, and **continuous quality improvement**. A passionate educator, she collaborates with **Jan Kochanowski University, Collegium Medicum, AIDIFY**, and the **Polish Association for Good Clinical Practice (GCPpl)**, delivering specialized training on GCP, audit preparation, and quality systems.

Dr. Sokol holds a **PhD and MSc in Biology** from the **University of Warsaw**, and a **Postgraduate Diploma in Bioethics and Medical Law** from **Cardinal Stefan Wyszyński University**. A certified coach (SET Academy, Warsaw) and active member of GCPpl, she is dedicated to advancing ethical, compliant, and high-quality clinical research globally.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - INTRODUCTION TO GOOD CLINICAL PRACTICE (GCP)

- Evolution of clinical research ethics
- Principles of ICH-GCP
- GCP scope and applicability
- GCP and quality management systems
- Common compliance challenges and case examples

MODULE 2 - ETHICS AND PARTICIPANT PROTECTION

- Role and composition of Ethics Committees
- Participant privacy and informed consent under GDPR
- Risk-benefit assessment principles
- Vulnerable populations and special considerations

MODULE 3 - INVESTIGATOR RESPONSIBILITIES

- Role of the Principal Investigator (PI) and delegation of duties
- Site staff training and qualification
- Vendor oversight
- Managing protocol deviations
- Communication with sponsor and monitors

MODULE 4 - SPONSOR RESPONSIBILITIES

- Sponsor obligations under GCP and CTR
- Oversight of outsourced activities and CRO management
- Trial Master File (TMF) management
- Risk-based quality management (RBQM)
- Sponsor monitoring and documentation standards

MODULE 5 - CLINICAL TRIAL GOVERNANCE IN THE EU

- Governance structures and regulatory oversight
- Role of the European Medicines Agency (EMA) and national authorities
- Coordination of multinational studies

MODULE 6 - EU CLINICAL TRIALS REGULATION (CTR) 536/2014 IN PRACTICE

- CTR objectives
- Clinical Trials Information System (CTIS): structure and workflow
- Transparency and public disclosure requirements
- Practical lessons learned since CTR implementation

PROGRAM AGENDA

MODULE 7 - CLINICAL TRIAL DESIGN AND PROTOCOL DEVELOPMENT

- Quality by design
- Critical to quality factors, KRIs and QTLs
- Elements of a strong protocol (Objectives, endpoints, design)
- Sample size and statistical justification
- Protocol amendments and version control

MODULE 8 - INFORMED CONSENT AND DOCUMENTATION STANDARDS

- Patient engagement
- Documentation per ICH-GCP and local regulations
- Handling of electronic consent (eConsent)
- Best practices for maintaining participant trust

MODULE 9 - MANAGING INVESTIGATIONAL MEDICINAL PRODUCTS (IMPS)

- GMP and labeling requirements
- Storage, temperature control, and accountability logs
- IMP distribution and return procedures
- IMP traceability and documentation

MODULE 10 - DATA MANAGEMENT AND BIOSTATISTICS

- Data capture systems (eCRF, EDC platforms)
- Data validation and query management
- Principles of data integrity (ALCOA+)
- Statistical analysis plan (SAP) fundamentals
- Data sharing and anonymization

MODULE 11 - SAFETY REPORTING AND PHARMACOVIGILANCE

- AE, SAE, SUSAR, and their differences in reporting
- Safety data collection at sites
- Timelines for expedited and periodic reporting
- Role of Data Safety Monitoring Boards (DSMBs)

MODULE 12 - POST-TRIAL OBLIGATIONS AND REPORTING

- Clinical Study Report (CSR) requirements
- Publication and transparency obligations (EudraCT, CTIS)
- Participant follow-up and results communication
- Data archiving and retention

PROGRAM AGENDA

MODULE 13 - AUDITS, INSPECTIONS, AND CAPA

- Inspection readiness
- Types of audits (System, process, trial-specific)
- Preparing for inspections (MHRA, EMA, FDA)
- Common inspection findings
- Root cause analysis and CAPA development
- Continuous improvement in QA system

MODULE 14 - GCP CERTIFICATION AND CONTINUOUS IMPROVEMENT

- Competency frameworks for GCP professionals
- Integration of lessons learned into SOPs
- Creating a culture of quality and ethics

MODULE 15 - FUTURE OF GCP IN EUROPE – TRENDS & UPDATES

- ICH E6(R3) and current industry needs
- Decentralized and hybrid trials (DCTs)
- Digital data sources and AI in clinical research
- Real-world evidence (RWE) integration
- Future of ethics, consent, and patient engagement

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 the EU 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.

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OUR FACULTY DIRECTORS

We Collaborate With Instructors From Renowned Institutions

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Stanford University

University of Michigan

LSE 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
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
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
Phone: +44 (020) 335 57898
Address: Chartered Institute of Professional Certifications
86-90 Paul Street
London, EC2A 4NE

USA Enquiries

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