CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

CERTIFIED UK CLINICAL TRIAL REGULATIONS AND COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

The UK's clinical trial environment ranks among the most advanced yet complex globally, **shaped by layered regulatory frameworks, evolving ethical standards, and post-Brexit divergence from the EU Clinical Trials Regulation (CTR).** Frequent updates to MHRA guidance, shifting expectations on GCP compliance, and differences in governance procedures across England, Scotland, Wales, and Northern Ireland create significant challenges for trial sponsors, investigators, and research professionals striving to maintain regulatory alignment while operating efficiently across the UK.

This certified program will equip you with a comprehensive understanding of the UK's clinical trial regulations and compliance requirements across all trial phases. You will explore a wide range of essential topics, including the **Medicines for Human Use (Clinical Trials) Regulations 2004, Human Medicines Regulations 2012, the UK Clinical Trial Regulation Reform 2024, and regulatory obligations under UK GDPR.** The program covers trial submissions, informed consent, ethics approvals via the UK Health Research Authority (HRA) and Research Ethics Committees (RECs), and compliance with MHRA expectations for sponsor oversight, documentation, safety reporting, and GCP adherence. It also highlights regulatory differences across the UK's devolved administrations.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

PROGRAM OVERVIEW

Throughout the program, you will gain the knowledge and skills to plan, manage, monitor, and close out clinical trials in full compliance with UK regulations. You will learn how to **apply current GCP principles, interpret MHRA guidance updates, and implement best practices in risk-based monitoring, data integrity, and audit readiness.** Additionally, the program offers hands-on insight into managing Trial Master Files (TMFs), developing Corrective and Preventive Action (CAPAs), responding to inspection findings, and maintaining high-quality documentation to meet MHRA inspection standards.

Moreover, this program provides practical guidance on emerging challenges such as digital and decentralized trial models, AI-driven protocol designs, and integrating real-world evidence while maintaining data privacy and ethical integrity. You will also explore **compliance needs for vulnerable populations, diversity in recruitment, and cross-border collaboration post-Brexit.**

Upon successfully completing the program, you will earn the **Certification in UK Clinical Trial Regulations and Compliance.** This certification will validate your ability to navigate the UK's regulatory landscape and execute compliant, ethical, and high-quality clinical trials. Globally recognized and valid for life, this credential enhances your professional credibility and demonstrates your readiness to lead clinical research projects across commercial, academic, and non-commercial settings.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

KEY SKILLS YOU WILL GAIN

From This Program

- UK CLINICAL TRIAL REGULATION 2004
- HUMAN MEDICINES REGULATION 2012
- MHRA COMPLIANCE
- GCP PRINCIPLES APPLICATION
- INFORMED CONSENT MANAGEMENT
- HRA/REC ETHICS SUBMISSIONS
- CTA SUBMISSION PROCESS
- SPONSOR OVERSIGHT PLANNING
- VENDOR MANAGEMENT
- TRIAL MASTER FILE (TMF) MANAGEMENT
- CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)
- MHRA INSPECTION READINESS
- RISK-BASED MONITORING (RBM)
- DATA INTEGRITY ALCOA+
- ADVERSE EVENT REPORTING
- GDPR-COMPLIANT DATA HANDLING
- PROTOCOL COMPLIANCE MANAGEMENT
- CROSS-BORDER TRIAL GOVERNANCE
- REAL-WORLD EVIDENCE INTEGRATION

YOUR FACULTY DIRECTOR

Charlotte Chadwick

Distinguished UK Clinical Research and Compliance Expert

Charlotte Chadwick is an esteemed expert in clinical research and regulatory compliance, bringing over 25 years of leadership across pharmaceutical companies, CROs, and clinical research sites. With **deep specialization in UK clinical trial regulations, early phase trials, and MHRA inspection readiness, she has guided numerous organizations through complex regulatory frameworks** with precision and confidence.

Charlotte has played a pivotal role in supporting multiple first-time and routine MHRA inspections, consistently achieving 100% compliance. Her technical expertise covers **GCP implementation, SOP development, sponsor oversight, ethics and regulatory submissions, and documentation systems.** As the founder of her own consultancy, she advises biotech firms, CROs, pharmaceutical companies, and clinical technology providers on inspection-readiness, compliance strategies, and operational optimization.

An accomplished educator, Charlotte has **over 15 years of experience delivering impactful training programs on clinical operations and regulatory compliance.** She is known for transforming complex regulatory topics into practical, engaging sessions using real-world case studies, scenario-based learning, and visual storytelling. Her workshops and CRA training modules are highly acclaimed for their clarity, relevance, and immediate applicability, empowering professionals to maintain the highest standards of ethical and regulatory conduct in clinical research.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - UK CLINICAL TRIAL REGULATIONS LANDSCAPE, EU VS. UK

Lesson 1: Legislative Framework
Lesson 2: Brexit Impact
Lesson 3: MHRA Structure

MODULE 2 - MHRA EXPECTATIONS & RECENT INSPECTION FINDINGS

Lesson 1: Current Trends
Lesson 2: Common Findings
Lesson 3: Inspection Focus Areas

MODULE 3 - GCP PRINCIPLES IN PRACTICE

Lesson 1: Application Of GCP In UK Trials
Lesson 2: Documentation
Lesson 3: Training Required To Understand These Principles

MODULE 4 - SPONSOR RESPONSIBILITIES & OVERSIGHT

Lesson 1: Oversight Plans
Lesson 2: Vendor Management
Lesson 3: Delegation Log

MODULE 5 - TMF & ESSENTIAL DOCUMENTS

Lesson 1: Filing Structure
Lesson 2: QC Process
Lesson 3: Document Lifecycle

MODULE 6 - RISK-BASED MONITORING & RISK MANAGEMENT

Lesson 1:Risk Assessments
Lesson 2: Mitigations
Lesson 3: Monitoring Strategies

MODULE 7 - INFORMED CONSENT & ETHICS SUBMISSIONS

Lesson 1: REC/HRA Process
Lesson 2: ICF Design
Lesson 3: Version Control

MODULE 8 - HANDLING PROTOCOL DEVIATIONS & CAPA

Lesson 1: Root Cause Analysis
Lesson 2: Corrective Actions
Lesson 3: Documentation

PROGRAM AGENDA

MODULE 9 - DATA INTEGRITY & AUDIT TRAILS

Lesson 1: ALCOA+
Lesson 2: Source Data
Lesson 3: Systems Compliance

MODULE 10 - PREPARING FOR AN MHRA INSPECTION

Lesson 1: Pre-Inspection Activities
Lesson 2: Interviews
Lesson 3: Documentation

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 UK Clinical Trial Regulations and Compliance** that can be used in your resume, CV and other professional credentials. This certification is industry-recognized with lifelong validity.

Globally respected and in high demand, this certification will amplify your expertise in conducting ethical, efficient, and fully compliant clinical trials in accordance with the UK's latest regulatory frameworks and MHRA expectations. It validates your capability to develop and implement robust clinical trial compliance systems aligned with UK legislation, GCP standards, and international best practices. This program is developed by **Chartered Institute of Professional Certifications** and the content of this program has been certified by **CPD Certification Service** as adhering to highest standards of continuing professional principles.

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.

OUR FACULTY DIRECTORS

We Collaborate With Instructors From Renowned Institutions

HARVARD UNIVERSITY

Wharton University of Pennsylvania

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