CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

EU CLINICAL TRIAL REGULATIONS AND COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

EU's clinical trials regulation constitutes a complex and comprehensive framework with over 500 pages of rigorous regulations. The regulations also require detailed reporting and transparency, necessitating extensive documentation. Furthermore, **the regulation imposes substantial penalties, exceeding €20 million for each instance of non-compliance**.

This certified program is designed to empower you with an in-depth understanding of clinical trials management, enabling you to effectively navigate the intricate legal and ethical terrains associated with clinical trials. You will delve into the **EU's legislative framework, clinical trial regulations** and its key compliance policies. It will also cover vital regulatory elements including **Good Clinical Practice (GCP) Compliance guidelines, clinical trials authorization process, subject protection and informed consent**. Moreover, you will gain insights into the clinical trial design and key documentation process, enabling you to draft required content for the trial protocol and create investigators brochures and necessary checklists helping you to maintain subject rights and confidentiality.

Throughout the program, you will also gain expertise into **pharmacovigilance and safety reporting protocols** which will help you to categorize adverse event types and assist in correct reporting of all safety information. This program will also provide insights into the application of **good manufacturing practice to clinical trials and the requirements for Investigational Medicinal Products (IMPs) and Auxiliary Medicinal Products (AxMPs)**. You will learn effective data management techniques and audit trail validation methods using computerized systems. By the end of the program, you will demonstrate the required expertise to navigate the complexities of EU clinical trial regulations and be equipped with the strategies to mitigate risk and ensure compliance.

Upon successfully completing the program, you will attain the highly respected **Certification in EU Clinical Trial Regulations and Compliance**, enhancing your professional credentials and amplifying your expertise in the vital area of clinical trials regulations. This industry-recognized certification offers lifelong validity and distinguishes you as an expert in managing ethically and legally compliant clinical trials.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

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4.6

KEY SKILLS YOU WILL GAIN

From This Program

EU CLINICAL REGULATORY COMPLIANCE
CLINICAL TRIALS REGULATION
GOOD CLINICAL PRACTICE
CLINICAL TRIAL APPLICATIONS

INFORMED CONSENT
CLINICAL TRIALS ADMINISTRATION
PHARMACOVIGILANCE
RISK ASSESSMENT

ETHICAL RESEARCH
GDPR COMPLIANCE
CLINICAL TRIAL AUDITING
CLINICAL TRIAL DESIGN
CLINICAL INVESTIGATIONS

SAFETY REPORTING
CLINICAL TRIAL INSURANCE
CLINICAL QUALITY ASSURANCE (CQA)
CLINICAL TRIAL REPORTING
EU CLINICAL TRIALS LEGISLATION

CLINICAL TRIALS AUTHORIZATION
CLINICAL DATA MANAGEMENT

YOUR FACULTY DIRECTOR

Jo Burmester

CEO and Clinical Research Training Consultant

Jo Burmester is an accomplished CEO and clinical research training consultant who has been an industry leader since 1987, renowned for her expertise in Good Clinical Practice (GCP) and ability to engagingly present complex topics. Her distinguished career began as a clinical research associate, then progressed through **managerial roles at global pharmaceutical and CRO organizations including Glaxo, Lederle, Wellcome, ClinTrials Research, and Quintiles**. This diverse experience imparted broad perspective and specialty in training, which Ms. Burmester has focused on since 1992.

As Co-Founder and former Director of the specialist training company PharmaSchool, she **spent 14 years collaborating with various institutions and medical entities to deliver impactful GCP and professional development programs**. Since 2018, Ms. Burmester has continued her influential training work as an independent consultant. She holds trainer certification from the Chartered Institute of Personnel and Development and formerly served as Module Leader at Liverpool John Moore's University. Ms. Burmester has **contributed to international clinical research forums, edited the online journal MedSquare, and authored a book on continuing professional development**. With renown for her dynamic presentation style, she remains a foremost expert in regulatory and compliance training, covering ICH GCP, clinical research legislation, trial monitoring, and GMP for investigational medicinal products.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - EVOLUTION AND CURRENT LANDSCAPE OF EU CLINICAL TRIALS

- Lesson 1 - EU Legislative Framework – Directives vs Legislation
- Lesson 2 - Key Objectives of the Regulation, Roles and Responsibilities
- Lesson 3 - Current Status and Implementation

MODULE 2 - ESSENTIAL TERMINOLOGY AND DEFINITIONS

- Lesson 1 - Key Terms Used in Clinical Trials and EU Legislation
- Lesson 2 - New Definitions in the Clinical Trials Regulation

MODULE 3 - AUTHORIZATION PROCESSES IN EU CLINICAL TRIALS

- Lesson 1 - Overview of the Clinical Trials Authorization Process
- Lesson 2 - Modifications
- Lesson 3 - Ethics Review

MODULE 4 - SUBJECT PROTECTION AND INFORMED CONSENT

- Lesson 1 - Participant Engagement
- Lesson 2 - Informed Consent
- Lesson 3 - Maintaining Subject Rights and Confidentiality

MODULE 5 - CLINICAL TRIAL DESIGN AND KEY DOCUMENTS

- Lesson 1 - Required Content for the Trial Protocol
- Lesson 2 - Investigators Brochure
- Lesson 3 - Information About the Investigational Medicinal Product

MODULE 6 - PHARMACOVIGILANCE AND SAFETY REPORTING

- Lesson 1 - Definitions and Adverse Event Categories
- Lesson 2 - Reporting Requirements, Responsiblities and Timelines
- Lesson 3 - Reference Safety Information

PROGRAM AGENDA

MODULE 7 - INVESTIGATIONAL MEDICINAL PRODUCTS (IMPS)

- Lesson 1 - Manufacture, Management and Accountability
- Lesson 2 - Storage and Dispensing
- Lesson 3 - Auxiliary Medicinal Products (AxMPs)

MODULE 8 - SPONSOR OVERSIGHT

- Lesson 1 - Sponsor Responsibilities and Demonstrating Oversight
- Lesson 2 - Management of Compliance (Including Monitoring and Audit)
- Lesson 3 - Reporting of Serious Breaches and Urgent Safety Measures

MODULE 9 - INVESTIGATOR OVERSIGHT

- Lesson 1 - Investigator Responsibilities
- Lesson 2 - Delegation at the Investigational Site
- Lesson 3 - Demonstration of Oversight

MODULE 10 - DATA MANAGEMENT, DOCUMENTATION AND COMPUTERISED SYSTEMS

- Lesson 1 - Data Integrity and the Audit Trail
- Lesson 2 - Validation and Maintenance of Computerised Systems
- Lesson 3 - Trial Master File and Essential Documents
- Lesson 4 - Archiving Requirements

MODULE 11 - CLINICAL TRIALS TRANSPARENCY AND REPORTING

- Lesson 1 - Registration on a Public Database
- Lesson 2 - Status Reporting Required Under the EU Clinical Trials Regulation
- Lesson 3 - Reporting of Results and EMA Policy on Publication

MODULE 12 - INSPECTIONS IN THE EU

- Lesson 1 - Who Conducts GCP Inspections in the EU?
- Lesson 2 - Overview of the Inspection Process
- Lesson 3 - Examples of Recent Inspection Findings

YOUR CHARTER DESIGNATION

Chartered Institute of Professional Certification's programs are unique as they provide you with professional charter designation and mark that can be used across your lifetime once your have completed our programs.

Upon successfully attending this program, you will be awarded with the **Certification in EU 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 demanded and recognized, this certification will amplify your professional qualifications and demonstrate your expertise in navigating the intricacies involved in EU clinical trials regulations and compliance strategies. 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

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 program are fully accredited programs. The professional charter 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.

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OUR FACULTY DIRECTORS

We Collaborate With Instructors From Renowned Institutions

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CONTACT US TODAY

We Thank You for Your Ongoing Support of Our Programs

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