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U.S. CLINICAL TRIAL MANAGEMENT AND REGULATORY COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

The clinical trial management and regulatory compliance landscape in the United States is not only intricate but also one of the most heavily regulated sectors globally. Navigating through the extensive array of laws and guidelines governing clinical trials can be daunting for even the most seasoned professionals. With over 5,500 clinical trials registered in the U.S. every year, understanding the evolving regulations is crucial to ensuring trial success and compliance. **The complexity deepens as regulatory bodies like the FDA continue to introduce new requirements, making non-compliance a costly risk — with fines that can reach up to $1 million per violation.**

This certified program is designed to provide participants with a comprehensive understanding of the clinical trial regulatory environment in the United States. You will gain valuable insights into critical areas **such as the FDA's regulatory structure, the International Council for Harmonisation (ICH) guidelines, the Code of Federal Regulations, and the implementation of Good Clinical Practice (GCP).** The program goes beyond regulations, emphasizing ethical considerations in clinical research and the sophisticated management of clinical trial operations, ensuring a robust understanding of both legal requirements and practical application.

Participants will explore the **intricate technical aspects of clinical trial conduct, mastering key areas such as the informed consent process, safety monitoring, adverse event reporting, and data integrity**. In addition, this program will cover the practical aspects of **clinical trial management, including trial design, budgeting, site selection, and strategies for patient recruitment—essential for maintaining both scientific rigor and operational efficiency**. You will be equipped with the tools to manage clinical trials effectively, ensuring they meet stringent regulatory standards while optimizing timelines and resources.

ACCREDITATIONS

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PROGRAM OVERVIEW

Furthermore, participants will learn **how to prepare for FDA inspections, navigating the complexities of regulatory audits, and effectively managing compliance challenges**. This program will arm you with strategies to minimize the risk of non-compliance, avoid costly delays, and ensure that your clinical trials adhere strictly to FDA guidelines.

Upon successful completion of the program, participants will be awarded the **Certification in U.S. Clinical Trial Management and Regulatory Compliance**. This certification will enhance your professional qualifications and demonstrate your critical knowledge in navigating the complex landscape of U.S. clinical trial regulations and compliance requirements. This industry-recognized certification is also a lifelong endorsement of your expertise and dedication to excellence in clinical research and regulatory affairs within the U.S. healthcare and pharmaceutical sectors.

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KEY SKILLS YOU WILL GAIN

From This Program

CLINICAL TRIAL OVERSIGHT
FDA REGULATORY KNOWLEDGE
ETHICAL CONSIDERATIONS IN TRIALS
CODE OF FEDERAL REGULATIONS (CFR)

GOOD CLINICAL PRACTICE (GCP) APPLICATION
CLINICAL PROTOCOL DEVELOPMENT
INVESTIGATORS' BROCHURE MANAGEMENT
ENDPOINTS AND STATISTICAL DESIGN

DECENTRALIZED CLINICAL TRIALS (DCT) MANAGEMENT
DIGITAL HEALTH TECHNOLOGIES IN TRIALS
REAL-WORLD EVIDENCE (RWE) INTEGRATION

ADVERSE EVENT REPORTING
DATA SAFETY MONITORING COMMITTEES (DSMC)
CLINICAL INVESTIGATOR RESPONSIBILITIES
INSTITUTIONAL REVIEW BOARD (IRB) PROTOCOLS
INFORMED CONSENT COMPLIANCE

QUALITY BY DESIGN (QBD) IMPLEMENTATION
CLINICAL DATA INTERCHANGE STANDARDS (CDISC)

YOUR FACULTY DIRECTOR

Dr. Jayanthi Wolf

Highly Distinguished Pharmaceutical and Regulatory Affairs Leader

Dr. Jayanthi is a highly regarded leader in the pharmaceutical industry with deep expertise in regulatory affairs. She currently **heads the regulatory affairs and quality assurance department at a Boston-based biotechnology firm** focused on developing innovative treatments for infectious diseases. Her career spans leadership roles in biotechnology and major pharmaceutical companies, where she contributed to the successful development of several breakthrough medicines. Notably, she **served as the global regulatory team leader for ERVEBO®, the first Ebola vaccine approved by the FDA, EMA, and prequalified by the WHO**.

Jayanthi holds a Ph.D. and master's degree in Molecular Biology and Immunology from Princeton University, along with a B.S. in Biochemistry from Susquehanna University. She has been **recognized with several prestigious awards, including for the approvals of KEYTRUDA® and GARDASIL-9®**. Jayanthi is an **active member of the Society of Toxicology, the Regulatory Affairs Professional Society, and serves on the Biotechnology Innovation Organization's Regulatory Affairs Steering Committee**.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - INTRODUCTION TO THE U.S. CLINICAL TRIAL PROCESS

- Oversight of Clinical Trials
- FDA Structure and Responsibilities
- Ethical and Legal Considerations

MODULE 2 - REGULATORY GUIDELINES FOR U.S. CLINICAL TRIALS

- ICH and FDA Guidelines
- Code of Federal Regulations
- Regulatory Processes Governing U.S. Clinical Trials

MODULE 3 - GOOD CLINICAL PRACTICE IN TRIAL MANAGEMENT

- Importance of Good Clinical Practice
- ICH E3 Good Clinical Practice Guideline

MODULE 4 - DESIGN OF CLINICAL TRIALS

- Basics of Clinical Trial Design
- Clinical Protocol Development
- Investigators Brochure
- Endpoints and Statistical Considerations

MODULE 5 - NEW TRENDS IN CLINICAL TRIAL DESIGN

- Decentralized Trials
- Digital Health Technologies
- Real World Evidence

MODULE 6 - SAFETY CONSIDERATIONS IN CLINICAL TRIALS

- Safety Monitoring in Clinical Trials
- Adverse Event Reporting
- Regulatory Guidelines for Safety Reporting
- Data and Safety Monitoring Committees

MODULE 7 - CLINICAL INVESTIGATOR RESPONSIBILITIES

- Study Protocol Development and Reviews
- Informed Consent Regulations
- Institutional Review Boards

MODULE 8 - BUILDING QUALITY INTO THE CLINICAL TRIALS

- Importance of Quality Management
- Sponsor's Role in Quality Oversight
- Principles of Quality by Design

PROGRAM AGENDA

MODULE 9 - DATA QUALITY AND RESULTS REPORTING

- Data Management Overview
- Data Collection and Case Report Form Development
- Clinical Data Interchange Standards (CDISC)
- Clinical Trials Registration, Results Reporting, and Data Sharing

MODULE 10 - PREPARING FOR FDA INSPECTIONS

- FDA's Inspection Programs
- Preparing for FDA Inspections
- Expectations After the FDA Inspection

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 U.S. Clinical Trial Management and Regulatory Compliance that can be used in your resume, CV and other professional credentials. This certification is industry-recognized with lifelong validity.

Globally recognized and highly sought after, the **Certification in U.S. Clinical Trial Management and Regulatory Compliance** will elevate your professional credentials and showcase your expertise in navigating the intricate landscape of U.S. clinical trial regulations. It will validate your ability to develop and implement a robust compliance framework that ensures your organization's clinical trial practices align with FDA standards and Good Clinical Practice (GCP) guidelines. Developed by the Chartered Institute of Professional Certifications, this program has been independently accredited by the CPD Certification Service, ensuring it meets the highest standards of continuing professional development 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.

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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

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