CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

EU PHARMACEUTICAL REGULATIONS AND COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

The EU's regulations on pharmaceuticals are among the strictest globally, **with a complex network of laws and directives implemented at both the EU and member state levels**. Navigating this multifaceted regulatory landscape can be challenging for pharmaceutical leaders, as they must comply not only with EU-wide standards but also with country-specific regulations that can vary significantly across the union.

This comprehensive certified program is designed to enhance your capabilities in compliance planning, regulatory submission processes, and effective management of drug safety audits and inspections within the European Union's pharmaceutical landscape. The program will equip you with a wide range of technical knowledge encompassing the **EU's pharmaceutical regulations, including an in-depth analysis of drug safety standards, quality management systems, clinical trial requirements, marketing authorization procedures, and the implications of non-compliance**.

You will gain intricate knowledge of critical pharmaceutical legislations, such as **Regulation (EC) No 726/2004 on Community procedures for the authorization and supervision of medicinal products, Good Manufacturing Practice (GMP) guidelines, and Pharmacovigilance requirements**. Throughout the program, you will delve deep into the technical intricacies of pharmaceutical regulations, **mastering clinical trial requirements, risk management strategies, quality control measures, and drug safety monitoring mechanisms**.

This program will also cover crucial aspects of regulatory compliance, enabling you to establish a robust framework to ensure your products meet all relevant laws and regulations. Additionally, it addresses the **legal complexities surrounding marketing authorizations, including dossier preparation, data exclusivity, and regulatory submission processes**. Key legal issues related to the enforcement of pharmaceutical regulations, risk assessment methodologies, and the handling of cross-border drug supply challenges within the EU market will be thoroughly examined.

Upon successfully completing the program, you will attain the highly respected **Certification in EU Pharmaceutical Regulations and Compliance**, signifying your advanced skills and deep knowledge in navigating the EU's complex pharmaceutical regulatory landscape. This industry-recognized certification will enhance your professional credentials and demonstrate your commitment to excellence in the EU's pharmaceutical sector.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

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KEY SKILLS YOU WILL GAIN

From This Program

PHARMACEUTICAL SAFETY STANDARDS
REGULATORY COMPLIANCE
DRUG APPROVAL PROCESS
MARKETING AUTHORIZATION PROCEDURES

EUROPEAN MEDICINES AGENCY (EMA) REGULATIONS
GOOD MANUFACTURING PRACTICES (GMP)
GOOD CLINICAL PRACTICE (GCP)

GOOD VIGILANCE PRACTICE (GVP)
QUALITY MANAGEMENT SYSTEMS (QMS)
ISO 9001 2015
CLINICAL TRIAL REGULATIONS

INSPECTION READINESS REQUIREMENTS
PLAN–DO–CHECK–ACT (PDCA) CYCLE
PHARMACOVIGILANCE
LABELLING & PACKAGING COMPLIANCE
POST-MARKET SURVEILLANCE

RISK BASED APPROACH IMPLEMENTATION
DOCUMENTATION MANAGEMENT

YOUR FACULTY DIRECTOR

Olga Olegovna Vorobjeva

Highly Esteemed Pharmacovigilance Expert and Certified ISO 9001:2015 Lead Auditor

Olga Vorobjeva is a distinguished quality and pharmacovigilance expert with over a decade of experience in the pharmacovigilance sector. She excels in establishing comprehensive quality management systems from the ground up, including the development of standard operating procedures, process mapping, and risk-based strategies. Her expertise extends to performing **Good Pharmacovigilance Practice (GVP) and quality audits, as well as third-party pre-qualifications**.

Olga has a robust background in implementing and maintaining ISO 9001 standards and GVP requirements. As a **certified lead auditor in ISO 9001:2015, she has conducted various types of pharmacovigilance audits, both internal and external**, and is experienced in hosting sponsor-related audits and regulatory inspections. As a subject matter expert in pharmacovigilance, she **specializes in risk-based audit planning, risk management, and vendor oversight**. Olga is also a member of the PIPA organization, a network of pharmacovigilance professionals and industry experts.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - INTRODUCTION TO PHARMA AND PHARMA REGULATIONS

- Lesson 1 - The International Dimension in Pharmaceuticals
- Lesson 2 - What is Distinctive About the Pharmaceutical Industry
- Lesson 3 - The Need for Specific Techniques for Pharmaceuticals

MODULE 2 - REGULATION FRAMEWORK – BRIEF OVERVIEW

- Lesson 1 - GMP
- Lesson 2 - GCP
- Lesson 3 - GVP

MODULE 3 - QMS REQUIREMENTS FOR PHARMA INDUSTRY

- Lesson 1 - Overview of QMS Standards (e.g. ISO 9001 2015)
- Lesson 2 - PDCA Cycle
- Lesson 3 - QMS Requirements

MODULE 4 - GCP REGULATIONS

- Lesson 1 - Requirements
- Lesson 2 - Concept
- Lesson 3 - Implementation

MODULE 5 - GMP REGULATIONS

- Lesson 1 - Requirements
- Lesson 2 - Concept
- Lesson 3 - Implementation

MODULE 6 - GVP REGULATIONS

- Lesson 1 - Requirements
- Lesson 2 - Concept
- Lesson 3 - Implementation

MODULE 7 - ROLE OF QUALITY ASSURANCE IN GXP

- Lesson 1 - Audits
- Lesson 2 - Inspections
- Lesson 3 - Risk Based Audit Program

MODULE 8 - MANAGEMENT OF THIRD PARTIES IN PHARMA

- Lesson 1 - Requirements for Outsourcing
- Lesson 2 - Qualification
- Lesson 3 - Management and Oversight

MODULE 9 - IT AND AI IN PHARMA

- Lesson 1 - Requirements
- Lesson 2 - Validation
- Lesson 3 - Implementation

PROGRAM AGENDA

MODULE 10 - TRENDS AND HOT TOPICS IN PHARMA

- Lesson 1 - Most Common Inspection Findings
- Lesson 2 - Channelings
- Lesson 3 - Innovation
- Lesson 4 - Future of Pharma Industry
- Lesson 5 - Local Specific Requirements in Various Countries

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 Pharmaceutical 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 intricate legal framework that governs pharmacovigilance and compliance within the European Union's comprehensive pharmaceutical regulations. 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

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CONTACT US TODAY

We Thank You for Your Ongoing Support of Our Programs

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