CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

EU PHARMACOVIGILANCE AND DRUG SAFETY REGULATIONS AND COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

The EU's pharmacovigilance legislation is ranked among the world's most stringent regulations globally. A recent survey by the European Federation of Pharmaceutical Industries and Associations (EFPIA) revealed that **75% of pharmaceutical companies find the complexity of these regulations a significant compliance challenge**. In addition, the legislation imposes strict timelines, such as submitting serious ADR reports within tight deadlines, and a 2023 industry survey showed that 68% of companies struggle to consistently meet these rigorous time frames.

This certified program is designed to equip you with an in-depth and comprehensive understanding of EU Pharmacovigilance and Drug Safety Regulations, as well as the complex compliance requirements necessary for navigating the pharmaceutical industry. Participants will gain knowledge on a wide range of critical subjects, including **a detailed examination of the EU regulatory framework, the core principles of pharmacovigilance, advanced risk management strategies, and sophisticated post-marketing surveillance methodologies**. Participants will also explore the **processes involved in adverse drug reaction (ADR) reporting**, including the collection, assessment, and submission of safety data in accordance with EU guidelines.

Throughout the program, participants will engage deeply in the key aspects of pharmacovigilance compliance, learning to **design and implement robust safety monitoring systems that meet EU regulatory requirements for medicinal products**. This includes mastering the **technical requirements for pharmacovigilance activities such as signal detection, the development of risk management plans (RMPs), and periodic safety update reports (PSURs)**. Additionally, the program will explore the intricacies of managing large pharmacovigilance data sets, employing advanced data analytics to detect safety signals, and crafting effective risk communication strategies to ensure transparent and timely information dissemination to stakeholders.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

PROGRAM OVERVIEW

Using real world case studies and practical examples, participants will also delve into the **role of pharmacovigilance inspections, audits, and the regulatory oversight mechanisms utilized by the European Medicines Agency (EMA) and national competent authorities (NCAs)** to ensure ongoing compliance. You will gain practical experience through detailed case studies and exercises, learning to navigate the legal and ethical challenges in drug safety, including the complexities of liability and patient confidentiality in pharmacovigilance.

Upon successful completion of the program, you will attain the **Certification in EU Pharmacovigilance and Drug Safety Compliance**. This distinguished certification will enhance your professional profile by demonstrating your expertise and comprehensive knowledge of the critical requirements for ensuring compliance with pharmacovigilance regulations and upholding the highest standards of patient safety throughout the drug lifecycle in the EU. The industry-recognized certification is valid for life, serving as a testament to your commitment to excellence in pharmacovigilance and drug safety management. We look forward to welcoming you to this program.

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

PHARMACOVIGILANCE REGULATORY FRAMEWORKS
ADVERSE DRUG REACTION (ADR) REPORTING
ADVERSE EVENT CLASSIFICATION

SIGNAL DETECTION AND ANALYSIS
RISK MANAGEMENT PLAN (RMP) DEVELOPMENT
GOOD PHARMACOVIGILANCE PRACTICES (GVP) IMPLEMENTATION

EUDRAVIGILANCE DATABASE MANAGEMENT
SAFETY SIGNAL PRIORITIZATION AND ASSESSMENT
POST-AUTHORIZATION SAFETY STUDY (PASS) DESIGN

PHARMACOVIGILANCE SYSTEM MASTER FILE (PSMF) MAINTENANCE
EMA GUIDELINES COMPLIANCE
REGULATORY DEADLINE MANAGEMENT
AUDIT AND INSPECTION PREPARATION

HEALTH AUTHORITY ENGAGEMENT STRATEGIES
BENEFIT-RISK EVALUATION

YOUR FACULTY DIRECTOR

Dr. Irene Michas

Highly Distinguished Global Pharmacovigilance and Regulatory Compliance Expert

Dr. Irene Michas is a seasoned professional in the field of pharmacovigilance with more than twenty years of experience in the pharmaceutical industry. She served as **Regional Safety Manager-Senior Director for the Asia, Africa and Middle East region at Pfizer Research and Development UK** where she managed and implemented new business initiatives and updates to procedures and systems. She has led working groups for the development and global implementation of numerous initiatives to facilitate compliance with pharmacovigilance requirements.

Dr. Michas' expertise also extends to **the development of comprehensive training programs to support the global rollout of new pharmacovigilance systems (e.g., Argus, ARISg)**, and in leveraging advanced technology for the development of e-learning programs. Her **in-depth knowledge of international pharmaceutical product regulations and extensive experience in various aspects of drug development activities** make her an exceptionally qualified professional in the field of pharmacovigilance.

Dr. Irene Michas is a Phi Beta Kappa scholar with a Bachelor of Arts degree in the field of Biological Basis of Behaviour from the University of Pennsylvania, USA, as well as an MSc and PhD in Psychology (Developmental, Cognitive, Experimental) from Reading University, UK.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - INTRODUCTION TO EU PHARMACOVIGILANCE

- Overview of Pharmacovigilance
- Key EU Regulatory Bodies and Their Roles
- Evolution of Pharmacovigilance Regulations in the EU

MODULE 2 - REGULATION FRAMEWORK – BRIEF OVERVIEW

- Structure of GVP Modules
- Key Concepts and Definitions
- Implementation and Compliance

MODULE 3 - ADVERSE EVENT REPORTING AND MANAGEMENT

- Definitions and Types of Adverse Events
- Adverse Event Reporting Systems
- Case Studies of Effective Reporting Practices

MODULE 4 - SIGNAL DETECTION AND RISK ASSESSMENT

- Methods for Signal Detection
- Analyzing and Prioritizing Safety Signals
- Tools and Technologies for Signal Detection

MODULE 5 - RISK MANAGEMENT PLANS (RMPS)

- Structure and Components of an RMP
- Developing an RMP
- Implementation and Monitoring of RMPs

MODULE 6 - PHARMACOVIGILANCE SYSTEM MASTER FILE (PSMF)

- Definition and Importance of the PSMF
- Creating and Maintaining a PSMF
- Regulatory Expectations for PSMF

MODULE 7 - POST-AUTHORIZATION SAFETY STUDIES (PASS)

- Purpose and Types of PASS
- Designing and Implementing PASS
- Regulatory Requirements and Reporting

MODULE 8 - PHARMACOVIGILANCE INSPECTIONS AND AUDITS

- Preparation for Inspections and Audits
- Key Areas of Focus During Inspections
- Common Findings and Best Practices

PROGRAM AGENDA

MODULE 9 - COMMUNICATION AND STAKEHOLDER ENGAGEMENT

- Communication Strategies for Safety Information
- Engaging with Health Authorities and the Public
- Case Studies of Effective Communication

MODULE 10 - FUTURE TRENDS IN PHARMACOVIGILANCE

- Emerging Technologies in Drug Safety
- Evolving Global Regulatory Landscape
- Innovations in Data Analysis and Reporting

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 EU Pharmacovigilance and Drug Safety 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, this certification will elevate your professional credentials and demonstrate your expertise in navigating the complex landscape of EU pharmacovigilance regulations. It will also validate your ability to implement a comprehensive compliance framework, ensuring your organization's drug safety practices align with the rigorous standards of the EU. Developed by the **Chartered Institute of Professional Certifications**, this program's content has been independently accredited by the **CPD Certification Service**, adhering to 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.

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

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