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UK MHRA MEDICAL PRODUCTS REGULATIONS AND COMPLIANCE

Fully Accredited By:

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PROGRAM OVERVIEW

The UK's MHRA medical products regulations rank among the world's most demanding regulatory frameworks. Since Brexit, organizations must **navigate diverging UK and EU requirements, extensive technical documentation, evolving regulatory guidance, rigorous clinical evidence standards, complex risk classification rules and intensive post-market surveillance obligations**. Coupled with strict enforcement and significant compliance costs, these requirements create a highly challenging regulatory environment that makes it difficult to achieve and maintain market approval.

This certified program will arm you with the comprehensive expertise to navigate UK MHRA requirements and lead compliance initiatives across medical products with confidence. You will build in-depth command of the domains that count — **MHRA frameworks for medicines and devices, product classification and approval pathways, clinical trial and clinical investigation requirements, and Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) standards**. You will also gain practical expertise in **pharmacovigilance systems, adverse event reporting, risk management frameworks**, and the preparation of regulatory submissions built to meet MHRA expectations.

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PROGRAM OVERVIEW

Beyond that, you will develop advanced competencies to **weave regulatory requirements into full product lifecycle management** — securing compliance from early development through commercialization and post-market monitoring. You will master **regulatory strategy, navigate UKCA marking requirements, manage MHRA interactions directly, and adapt fluidly to ongoing reforms** and evolving guidance. You will also gain real expertise in inspection readiness, audit management, and building quality management systems that meet MHRA standards while minimizing regulatory risk and delay.

Upon successful completion, you will earn the **Certification in UK MHRA Medical Products Regulations and Compliance** — an industry-recognized credential that validates your ability to lead regulatory compliance, strengthen quality governance, and drive innovation across the pharmaceutical, biotechnology, medical device, and healthcare industries.

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KEY SKILLS YOU WILL GAIN

From This Program

MHRA REGULATIONS COMPLIANCE
REGULATORY STRATEGY DEVELOPMENT
MARKETING AUTHORIZATION MANAGEMENT
REGULATORY SUBMISSION PREPARATION

CLINICAL TRIAL GOVERNANCE
CLINICAL TRIAL AUTHORISATION (CTA) MANAGEMENT
ETHICS APPROVAL MANAGEMENT

GOOD MANUFACTURING PRACTICE (GMP)
GOOD DISTRIBUTION PRACTICE (GDP)
GOOD CLINICAL PRACTICE (GCP)
GOOD LABORATORY PRACTICE (GLP)

QUALITY MANAGEMENT SYSTEMS
PHARMACOVIGILANCE SYSTEMS
SIGNAL DETECTION
RISK MANAGEMENT
REGULATORY INSPECTION READINESS

AUDIT PREPARATION
MEDICAL DEVICE CLASSIFICATION

YOUR FACULTY DIRECTOR

Dr. Brian Edwards

Leading Expert in UK Regulatory Affairs, Medical Safety, and Global Pharmacovigilance Excellence

Dr. Brian Edwards is a UK General Medical Council (GMC)-registered physician with over 30 years of experience in pharmacovigilance, regulatory affairs, clinical research, and medical safety. A **former Senior Medical Assessor at the UK's Medicines Control Agency** (now the Medicines and Healthcare products Regulatory Agency), he played a pivotal role in adverse event assessment, marketing authorization variations, regulatory decision-making, and European pharmacovigilance initiatives. He has also held senior leadership positions at global pharmaceutical companies and contract research organizations, including Parexel and Janssen.

Currently, Dr. Edwards **advises pharmaceutical and biotechnology organizations on pharmacovigilance systems, Good Pharmacovigilance Practice audits, regulatory submissions, inspection readiness, and marketing authorization strategies** across the UK and international markets. A **former Vice-President of the International Society of Pharmacovigilance (ISoP), published author, and respected international speaker**, he is widely recognized for translating complex regulatory requirements into practical, implementation-focused solutions for industry professionals.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - FOUNDATIONS OF UK REGULATION

- UK Regulatory Architecture & Legal Framework
- Evolution Post-Brexit
- UK Medicines and Devices Legislation
  Role of:
  - Medicines and Healthcare Products Regulatory Agency
  - National Institute for Health and Care Excellence
  - Health Research Authority
- Interaction with EU Systems, ICH, ISO and WHO
- Enforcement Powers and Criminal Liability

MODULE 2 - MEDICINES REGULATORY PATHWAYS

- Marketing Authorization Pathways
- National MA Procedures
- International Recognition Procedure
- Reliance Routes
- Conditional Approvals
- Orphan Medicines
- Innovative Licensing and Access Pathway (ILAP)
- Variations and Lifecycle Management
- Labelling and SmPC Requirements

MODULE 3 - MHRA OPERATIONAL PROCESSES

- MHRA Scientific Advice
- Submission Portals
- Validation Procedures
- Deficiency Letters
- Inspection Triggers
- GxP Inspection Process
- Enforcement Actions
- Recalls and Defect Reporting

MODULE 4 - CLINICAL TRIALS & RESEARCH GOVERNANCE

- UK Clinical Trial Requirements
- Combined Review Service
- CTA Submissions
- Ethics Approvals
- IMP Management
- Safety and SUSAR Reporting
- Decentralized Trials
- Data Integrity
- GCP Inspections

MODULE 5 - MEDICAL DEVICES & UKCA COMPLIANCE

- UK MDR 2002
- Device Classification and UKCA Marking
- Approved Bodies
- Technical Documentation

PROGRAM AGENDA

- Clinical Evaluation
- Software as a Medical Device
- Cybersecurity Obligations
- Human Factors Engineering
- UDI Systems

MODULE 6 - POST-MARKET SURVEILLANCE & VIGILANCE REPORTING

- Post-marketing Follow Up
- Trend Reporting
- Field Safety Corrective Actions
- PSUR Requirements
- Signal Detection
- Device Incident Investigations

MODULE 7 - PHARMACOVIGILANCE SYSTEMS

- UK PV Legislation
- QPPV Role
- PSMF Structure
- Signal Detection and Risk Management Plans
- Aggregate Reporting
- Literature Monitoring
- Vendor Oversight
- Inspection Readiness

MODULE 8 - QUALITY MANAGEMENT SYSTEMS & MANUFACTURING

- GxP & Quality Frameworks
  - GMP
  - GDP
  - GCP
  - GLP
  - ISO 13485
  - ICH Q9/Q10/Q12
- Data Integrity
- Supplier Qualification
- Deviation/CAPA Systems
  - Change Control and Risk Management

MODULE 9 - INTEGRATED PRODUCT LIFECYCLE STRATEGY

- End-to-End Product Lifecycle Management
  - From Discovery to Post-market
  - Regulatory Intelligence
  - Cross-functional Governance
  - Lifecycle Optimization
  - Inspection Readiness
  - Crisis Management
  - Digital Transformation
  - AI in Regulatory Systems

PROGRAM AGENDA

MODULE 10 - SPECIALIST TRACKS

- Advanced Therapy Medicinal Products
  - GMO Considerations
  - Chain of Identity/ Custody
  - Hospital Exemption
  - Vector Safety
  - Potency Assays
- AI & Digital Health
  - Adaptive Algorithms
  - Cybersecurity
  - Software Lifecycle Standards
  - AI Explainability
  - MHRA AI Roadmap
- Combination Products
  - Borderline Classification
  - Integrated Submissions
  - Human Factors
  - Device-drug Interactions

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.

On successfully completing this program, you will earn the **Certification in UK MHRA Medical Products Regulations and Compliance** — an industry-recognized certification with lifelong validity. This prestigious certification validates your expertise in UK medicines and medical device regulatory compliance, clinical research governance, and regulatory inspection readiness. It distinguishes you as a trusted regulatory authority, ready to secure successful product approvals, strengthen quality systems, and drive regulatory excellence across the pharmaceutical, biotechnology, and medical device industries.

This program is developed by the **Chartered Institute of Professional Certifications**, and its content has been certified by the **CPD Certification Service** as conforming to Continuing Professional Development principles.

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We Thank You for Your Ongoing Support of Our Programs

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