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EU MEDICAL DEVICE REGULATIONS AND COMPLIANCE

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

PROGRAM OVERVIEW

The transition to the **EU Medical Device Regulation (MDR) increased essential requirements from 18 to 22 classification rules, complicating compliance for manufacturers**. This expansion, aimed at enhancing safety and effectiveness, demands more resources and poses significant challenges in maintaining consistent market access across the EU.

This certified program is designed to equip you with essential skills for effective regulatory management and compliance in the medical device industry. This comprehensive program covers intricate aspects of **EU Medical Device Regulation (MDR) implementation, quality management systems, and clinical evidence requirements**, enabling you to navigate complex regulatory landscapes with confidence and expertise. Through an in-depth exploration of topics such as the **fundamental principles of device classification, conformity assessment procedures, and risk management strategies**, you will enhance your regulatory understanding and refine your ability to ensure product safety and compliance.

The program will also offer invaluable insights into **technical documentation preparation, post-market surveillance techniques, and the nuances of interactions with notified bodies**. Additionally, you will learn effective **methods for clinical evaluation, use of the European database on medical devices (EUDAMED) database, and techniques to demonstrate conformity with General Safety and Performance Requirements (GSPR)** while addressing regulatory challenges, thereby crafting robust compliance strategies.

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PROGRAM OVERVIEW

Moreover, this program will provide you with comprehensive guidance on **ISO 13485 and ISO 14971 standards, aligning them with specific MDR requirements and exploring strategies for implementing effective Quality Management Systems (QMS) and risk management**. Finally, you will learn about the clinical evaluation process, including the establishment of state-of-the-art practices, planning for conformity, and the continuous collection of clinical evidence throughout the device lifecycle.

Upon successful completion of the program, you will receive the **Certification in EU Medical Device Regulations and Compliance**, enhancing your professional credentials and demonstrating your mastery in ensuring product safety, efficacy, and regulatory adherence. This industry-recognized certification which offers lifelong validity not only boosts your professional profile but also prepares you to handle the complexities of EU medical device compliance with confidence and expertise.

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KEY SKILLS YOU WILL GAIN

From This Program

MEDICAL DEVICES DIRECTIVE (MDD)
MEDICAL DEVICES REGULATIONS (MDR)
COMPLIANCE IVDR UNDERSTANDING
DEVICE CLASSIFICATION

RISK ASSESSMENT
QUALITY MANAGEMENT ISO 13485 COMPLIANCE
ISO 14971 APPLICATION
CLINICAL EVALUATION

REGULATORY SUBMISSIONS
QUALITY MANAGEMENT SYSTEMS (QMS)
NOTIFIED BODY INTERACTION
TECHNICAL DOCUMENTATION

POST-MARKET SURVEILLANCE
ADVERSE EVENT REPORTING
EUDAMED DATA MANAGEMENT
CLINICAL DEVELOPMENT PLAN (CDP)
DECLARATION OF CONFORMITY (DOC) POST-MARKET CLINICAL FOLLOW-UP (PMCF)

UNIQUE DEVICE IDENTIFICATION (UDI) SYSTEM
PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE (PRRC)

YOUR FACULTY DIRECTOR

Asha Jacob

Distinguished Leader in Regulatory Affairs and Compliance

Asha Jacob is a distinguished leader in regulatory affairs and compliance within the MedTech industry, boasting an impressive 18-year career. Her expertise spans across **R&D, regulatory affairs, clinical affairs, medical writing, quality assurance, and quality management**. Currently, she serves as the Head of the Regulatory Affairs and Compliance team at Philips Medical Systems in the Netherlands. Asha also holds the crucial roles of **EU Authorized Representative Officer for EU MDR & EU IVDR and Person Responsible For Regulatory Compliance-2 at Philips**.

Asha's holistic, cross-functional understanding of EU MDR has enabled her to guide both business and market organizations through regulatory complexities. Her expertise is further validated by **BSI training in MDR Implementation for CE Marking and CQI & IRCA ISO 13485:2016 Auditor/Lead Auditor Certification**, underscoring her commitment to maintaining the highest standards in regulatory affairs and compliance.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - INTRODUCTION TO EU MEDICAL DEVICE REGULATION

- Historical Context and Evolution From MDD to MDR
- Key Changes and Their Implications
- Transition Timelines and Current Status

MODULE 2 - CONFORMITY ASSESSMENT AND NOTIFIED BODIES

- Medical Device Qualification
- Risk Classification
- Selection of Notified Bodies
- Conformity Assessment Procedures

MODULE 3 - QUALITY MANAGEMENT SYSTEMS (QMS) FOR MEDICAL DEVICES

- ISO 13485:2016 Requirements
- Integration with MDR Requirements
- Audits and Continuous Improvement

MODULE 4 - RISK MANAGEMENT AND POST-MARKET SURVEILLANCE

- Risk Management Process (ISO 14971)
- Vigilance and Post-Market Surveillance System
- Reporting of Adverse Events and Field Safety Corrective Actions

MODULE 5 - CLINICAL STRATEGY AND EVIDENCE REQUIREMENTS FOR REGULATORY AND HTA COMPLIANCE

- Clinical Evaluation Strategy
- Clinical Development and Evidence Planning
- Product Analysis and Market Positioning

MODULE 6 - REGULATORY STRATEGIES FOR NAVIGATING REGULATORY COMPLIANCE, MARKET ACCESS, AND MAINTENANCE

- Product Planning and Regulatory Strategy
- Compliance and Certification Process
- Product Lifecycle Management

MODULE 7 - TECHNICAL DOCUMENTATION AND CLINICAL EVALUATION

- Content Requirements for Technical Files
- Clinical Evaluation Process and Reporting
- Post-Market Clinical Follow-Up (PMCF)

MODULE 8 - EU UDI SYSTEM AND EUDAMED DATABASE

- Unique Device Identification (UDI) System Requirements
- EUDAMED Database Functionality and Access
- Data Submission and Compliance Challenges

PROGRAM AGENDA

MODULE 9 - OPERATORS AND SUPPLY CHAIN COMPLIANCE

- Economic Operators (EOs) in the Medical Device Industry
- Regulatory Interactions and Compliance
- Liability and Risk Management

MODULE 10 - LEADERSHIP INSIGHTS AND STAKEHOLDER COMMUNICATION

- Regulatory Expertise and Continuous Learning
- Compliance and Quality Improvement
- Organizational Culture and Stakeholder Engagement

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 Medical Device 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 underscores your expertise in managing complex regulatory environments, elevating your professional standing and effectiveness in ensuring medical device compliance across international markets. This program is developed by **Chartered Institute of Professional Certifications** and the content of this program has been certified by **CPD Certification Service** as conforming to 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 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 SCHOO OF ECONOMICS AN 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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