Medical Devices Online Course

£249

Course Overview

This course provides a practical introduction to managing medical device projects and clinical investigations within the current EU Medical Device Regulation (MDR) framework, supported by ISO 14155:2020, ISO 13485, and other relevant international standards. It reflects current expectations from global regulatory authorities, including the FDA and MHRA.

The course takes a risk-based, quality-focused approach to the medical device lifecycle, covering development, clinical investigation, regulatory approval, and post-market activities. Key themes include participant safety, data integrity, and regulatory compliance.

Learning Objectives

- Explain the medical device lifecycle under current MDR and relevant international standards.
- Apply a risk-based, quality-focused approach to medical device projects and clinical investigations.
- Maintain oversight of critical processes and data to support MDR and ISO 13485 compliance.
- Support the planning and oversight of clinical investigations to ensure participant safety and data integrity.
- Develop and maintain essential device documentation to ensure regulatory compliance and inspection readiness.

Module One:

- What is a Medical Device?
- Regulatory and Advisory Bodies
- Regulations, Guidelines and Standards
- ISO 14155:2020 Roles, Responsibilities and Monitoring
- Device Classification
- Defining Risk in Medical Devices
- Pre-Market Device Approval
- Submission and Approval Pathways

Module Two:

- Clinical Investigation Design & Conduct
- Clinical Investigation Planning
- Safety Reporting
- Clinical Evaluation Plan and Clinical Evaluation Reports
- Data Integrity
- Electronic Data Capture (EDC) Systems
- Roles and Responsibilities in the Device Industry
- Human Factors & Usability

Module Three:

- Ethical Data and Privacy Considerations
- Informed Consent
- Protecting Medical Devices from Cyber Attacks
- Audits
- Market Access & Device Approval Pathways
- Summary and Scenarios
- Course Exam

Duration: Approx. 6 hours

As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.