



The Faculty of Pharmaceutical Medicine has approved this course for CPD.

CPD points available: 6

## About This Course

This is a professionally developed Medical Device training course which incorporates the Medical Devices Report (MDR) implemented in June 2017, along with ISO 14155 and in addition to regulatory guidance from the FDA and MHRA. The Medical Devices Report (MDR), supersedes the previous Medical Devices Directive (MDD).

## Who is the course suited to?

This is a professionally developed, interactive and engaging online course essential for anyone working with Medical Devices. It is suitable for all levels of experience.

### Module 1

- What is a Medical Device?
- Device Classification
- Defining Risk in Medical Devices
- What is a CE mark?

### Module 2

- Regulatory, Advisory and Notified Bodies
- Regulations, Guidelines and Standards
- ISO 14155:2020: Key Players

### Module 3

- Clinical Investigation Planning
- Safety Reporting
- Clinical Evaluation Plan and Clinical Evaluation Reports
- Electronic Data Systems
- Roles and Responsibilities

### Module 4

- Informed Consent
- Marketing a Device in the U.S.
- Protecting Medical Devices from Cyber Attacks

### Module 5

- Summary
- Course Exam

**Price:** £249 inc. VAT (discount available for 6 or more users).

**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.



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info@trainingonline4u.com