SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

The Medical Device Regulation (CE Marking Process Key Updates)

LS026

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The Medical Device Industry is currently transitioning from the Medical Device Directive (MDD) 93/42/EEC to the Medical Device Regulation (MDR) 2017/745. As an industry we need to progress through this transition period in order to keep our products on the European Market and retain our CE mark. It is important therefore that we understand the MDR requirements and the key changes this entails for our products so that we can navigate through this change.

This course will look at steps involved in the CE marking process through the MDR (what remains the same, what has changed) as well as other key changes that are required. This course will also link the ISO 13485:2016 quality management system (QMS) requirements to the MDR QMS requirements but emphasizing the importance of the MDR as a legal requirement. This course will break down the MDR requirements into something more manageable and participants will gain the skills to be able to apply the requirements to their own products and understand the language used within the document.

Duration & Price

Duration: 1 day
Public Virtual Training: £350
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
10 Mar 2026	Virtual	Book Date

In-Company Training

Please contact us for more information on our In-Company training options

What's covered?

This course will have specific focus on the MDR 2017/745 and key areas that the medical device industry are currently transitioning through. This includes:

- Parties Involved
- Key Elements & high-level overview of the MDR
- Guide to the CE Marking Process
- Medical Device Regulation Classification including Classification Exercises
- Conformity Assessment Route Options
- Safety & Performance Requirements
- MDR QMS requirements. Linking them to the ISO EN 13485:2016 requirements (similarities & deficiencies)
- Other key changes within the MDR
- CE Marking Exercise

NOTE: Please bring a copy of the MDR with you to the course. Only certain elements of the MDR will be provided in the course material due to the content size of the regulation. A free copy can be downloaded from here.

Who should participate?

The course is suitable for personnel from medical device manufacturing industries (both legal manufacturers and contract manufacturers) who need to have a working knowledge/understanding of the MDR. It would be of particular interest to personnel who are required to liaise with notified bodies, who need to understand the CE marking process or who are involved in internal auditing.

What will I learn?

Participants achieve the following learning outcomes from the programme;

- Understand the main elements & structure of the MDR
- Have a working knowledge of the relevant key CE Marking Articles & Annexes within the MDR.
- Classify devices according to the MDR
- Understand the conformity assessment route options
- Understand all the steps involved in the CE marking process
- Appreciate what is entailed within the safety & performance requirements
- Understand how the MDR QMS requirements and ISO EN 13485:2016 QMS requirements link together (similarities & deficiencies)
- Be aware of the key changes within the Medical Devices Regulation
- Identify guidance documents available

How do we train and support you?

In-House Courses

The Course Tutor will contact your organisation in advance. In-house courses can be customised to meet your organisation's specific requirements.

NOTE: This course can be coupled with the ISO 13485:2016 training program to run onsite as a two-day programme.

Course Manual

Delegates will receive a very comprehensive course manual.

Tutors

John Lafferty
View Profile

Kevina O’Donoghue
View Profile

What Our Learners Say

We believe in excellence through transparency and continuous improvement. That's why we invite all our delegates to share their experiences on CourseCheck.com, an independent platform dedicated to genuine, unfiltered feedback. Learner insights help us not only to enhance our training programmes but also empower potential learners to make informed decisions. Click on the link below to read firsthand experiences and testimonials from past learners.

Click Here

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