SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY











ISO 13485:2016 & The Medical Devices Regulation (CE Marking Process)

LS021

ISO 13485:2016 & The Medical Devices Regulation (CE Marking Process)

This programme is available In-House and delivered through virtual classroom training.

ISO EN 13485:2016 is the global Quality Management Systems Standard used by medical device manufacturers to meet certain requirements to support the safety and effectiveness of the products they sell. Notified Bodies can use this standard when assessing whether companies have a QMS, which meets European Regulation requirements. Such an assessment is required where a manufacturer seeks to apply the CE mark. This means that companies must be conversant with ISO EN 13485:2016, the significant aspects of the regulations, relevant guidance standards and the CE mark process.

Duration & Price

Duration: 2 days
Delivery mode: This programme is available In-Company

Dates & Locations

In-Company training programmes are customised for your organisations specific needs. Most In-Company training is now delivered virtually.

In-Company Training

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

What's covered?

Day One has a specific focus on the ISO EN 13485:2016 QMS standard and includes:

- Course Objectives & Introduction
- Complete Overview of all sections of ISO EN 13485:2016 including a detailed focus on the updates to the standard.

Day Two has a specific focus on the MDR 2017/745 and the CE Marking Process. This includes:

- Parties Involved
- Key Elements & high-level overview of the MDR
- Guide to the CE Marking Process
- Medical Device Regulation Classification
- Classification Exercises
- Conformity Assessment Route Options
- Linking the ISO EN 13485:2016 requirements to the MDR QMS requirements
- 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 who need to have a working knowledge of ISO EN 13485:2016 and 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 requirements of ISO EN 13485:2016 including the updates
- Understand the main elements & structure of the MDR
- Have a working knowledge of the relevant key CE Marking 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
- Understand how ISO EN 13485:2016 QMS and the MDR 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

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

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

SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

SQT provide a unique combination of high quality, accredited, practical training delivered by leading industry experts and supported by the most up to date learning technology and tools

LEAN SIX SIGMA, PROCESS & PROJECT MANAGEMENT

- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

COMPLIANCE, STANDARDS & AUDITING

- Quality
- Environment & Energy Management
- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

QQI AWARD | IEMA APPROVED | CompEx Part of the JTL Group | FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE | CQI IRCA APPROVED TRAINING PARTNER | Chartered Institute of Environmental Health

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