SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY

ISO 13485:2016

LS028

ISO 13485:2016

ISO EN 13485:2016 is the global harmonized Quality Management Systems Standard used by medical device manufacturers to meet certain requirements to support the safety and effectiveness of the products they sell into Europe. ISO EN 13485:2016 was published on 26th February 2016 and has now completed its transition period since April 2019.

This Standard specifies requirements for a Quality Management System (QMS) that can be used by an organisation involved in one or more stages of the life cycle of a medical device including the design & development, production, storage & distribution, installation, servicing & final decommissioning & disposal of medical devices.

It can be used by external parties to assess the organisations ability to meet customer & regulatory requirements or Notified Bodies can use this standard when assessing whether companies have a QMS, which supports the European Directive/Regulation requirements. Such an assessment is required where a manufacturer seeks to apply the CE mark. This means that personnel within this industry must be conversant in the ISO EN 13485:2016 requirements, if they are certified to this standard.

Duration & Price

Duration: 1 day
Public Virtual Training: €425
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
09 Mar 2026	Virtual	Book Date

In-Company Training

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

What's covered?

- Course Objectives & Introduction
- ISO 13485:2016 – all sections of ISO 13485:2016, with focus on the updates. This will be discussed in a discussion-based environment and using tutors experience with the Standard. This allows participants to interact and discuss their current systems / processes in operation, how well these meet the requirements or if there are any challenges they may be experiencing.

The tutor is experienced in auditing against this standard and so will share experiences on expectations and outcomes from this standard in practice.

Who should participate?

The course is suitable for all personnel from medical device manufacturing or service/support industries who need to know the ISO 13485:2016 requirements or who may need a refresher of these requirements. Personnel who perform both internal audits or external audits on suppliers may also require this knowledge.

What will I learn?

Participants will achieve the following learning outcomes from this programme;

- Understanding the specific requirements of ISO EN 13485:2016 (including what new requirements have been included, what requirements have been removed, what remains the same)
- Awareness of what auditors may look for

How do we train and support you?

In-House Courses

Course tutor will contact your organisation in advance to discuss the programme in detail.
In-house courses can be customised to meet your organisation's specific requirements.

NOTE: This course can be coupled with The Medical Device Regulation (CE Making Process & Key Updates) training program to run onsite as a two-day programme.

Course Manual

Delegates will receive a hardcopy course manual with relevant course materials.

Tutors

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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