SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY











Medical Device Usability and EN IEC 62366

LS040

Medical Device Usability and EN IEC 62366

Use errors caused by inadequate medical device usability have become a growing concern for regulators, manufacturers and healthcare providers. It is the responsibility of medical device manufacturers to reduce all risk as far as possible, including usability-related risks. This highly interactive one-day training course provides a clear pathway to understanding and applying EN IEC 62366, together with guidance from the MHRA and US FDA, enabling learners to achieve compliance and apply the standard effectively to minimise usability-related risks. The course guides attendees thought the establishment of a Usability Process, how to achieve compliance with EN IEC 62366 and how to use the standard to minimise usability-related risks. The course involves interactive group exercises throughout.

We can tailor the training to meet your specific training needs and incorporate examples from your processes and procedures into the training programme as required.

Duration & Price

Duration: 1 day
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?

This course provides a detailed exploration of EN IEC 62366 requirements and their practical application. The training examines the usability engineering process and how it supports compliance and safety.

Topics include:

- MDR regulatory framework for Usability Engineering
- Relationship between EN IEC 62366, EN ISO 14971, and EN IEC 60601-1-6
- Usability Engineering Process overview
- Documentation requirements for new and legacy products
- Development of Use Specifications
- Task Analysis
- Risk assessment - identification of potential use errors, hazards, and hazardous situations
- Formative and summative evaluation processes and reporting
- Addressing User Interfaces of Unknown Provenance (UOUP)
- Integration of MHRA and FDA usability guidance with EN IEC 62366

The training involves practical exercises, with learners encouraged to apply principles to examples from their own workplace. If required, content may be tailored to reflect your organisation’s specific processes, risk profile, and regulatory setting.

Who should participate?

This course is designed for professionals in the medical device industry who require a solid grounding in Usability and Human Factors Engineering. The training is particularly beneficial for those involved in:

- Engineering and product development
- Quality assurance and regulatory compliance
- Risk management
- Medical device software and hardware design and development

A good standard of written and spoken English is important to engage effectively with this programme.

What will I learn?

On successful completion of this course, learners will be able to:

- Identify the EU and US regulations relating to Usability Engineering and Human Factors assessment.
- Explain the steps involved in establishing and maintaining a Usability Engineering process.
- Prepare and evaluate the required documentation for usability compliance in both new and legacy products.
- Develop and apply effective Use Specifications and hazard-related use scenarios.
- Conduct formative and summative evaluations and prepare the associated reports.
- Utilise EN IEC 62366 in conjunction with EN ISO 14971 and EN IEC 60601-1-6.
- Implement requirements for User Interfaces of Unknown Provenance (UOUP).

These outcomes ensure that learners return with the practical skills and knowledge necessary to usability engineering projects and prepare the required usability-related documentation and reports.

How will I be assessed?

To consolidate learning and reinforce key concepts, learners complete a **post-course** assessment. The assessment:

- Checks understanding of course content and practical scenarios
- Evaluates applied knowledge of usability and risk principles
- Is completed within one week of course completion

Successful learners receive a Certificate of Achievement in addition to their Certificate of Attendance.

How do we train and support you?

Our training approach is practical, highly interactive, and discussion-based, with flexibility to meet organisational needs

- Pre-training consultation for in-company courses to tailor content to organisational needs
- Emphasis on industry specific application through practical exercises, case studies, and group activities that reinforce key concepts and encourage active participation.
- Access to comprehensive course material that is regularly reviewed and updated to reflect the latest industry standards and guidance.
- Live training is available virtually or delivered onsite to suit the needs of the team
- Real-time support from expert tutors

Class sizes are generally limited to 12-15 participants to support personalised learning and individual support.

How can you progress?

Learners who complete this course often continue to deepen their skills in:

- Medical Device Risk Management and ISO 14971:2019
- Validation of Software as a Medical Device and EN IEC 62304
- Software Validation (for Production and QMS applications)
- 21 CFR Part 11 Electronic Records and Electronic Signatures and Data Integrity
- ISO 13485:2016 & The Medical Devices Regulation (CE Marking Process)
- Technical Writing Skills

Tutors



John Lafferty
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

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