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 an increasing cause for concern for Regulators, Medical Device Manufacturers and Healthcare providers alike. Many of the Medical Devices developed without applying a Usability (Human Factors) Engineering process are non-intuitive, difficult to learn and difficult to use. It is the responsibility of the Medical Device manufacturer to reduce all risk as far as possible including usability-related risks. A functioning Usability Engineering process is essential for the Medical Manufacturer in attempting to minimise risk associated with the usability of their devices. This course outlines the requirements for a Usability Process as defined by EN IEC 62366 and the guidance available from the MHRA and the US FDA. 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. The training includes an end-of-course assessment which helps to embed the learning. Attendees who pass the assessment receive a certificate of achievement.

Duration & Price

Duration: 1 day
Delivery mode: This programme is available In-Company

Dates & Locations

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In-Company Training

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What's covered?

Contents of EN IEC 62366

The course will examine in detail the requirements for establishment and maintenance of operation of a Usability Engineering Process in accordance with EN IEC 62304.
The course will be tailored from the perspective of a Notified Body rather than a manufacturer.

The requirements of EN IEC 62366 will be covered in detail including activities such as:

- MDR Regulatory framework for Usability Engineering
- Relationship between EN IEC 62366 & EN ISO 14971
- Relationship between EN IEC 62366 & EN IEC 60601-1-6
- Usability Engineering Process Overview
- Usability Engineering documentation required for new products
- Usability Engineering documentation required for legacy products
- Expectations for a Use Specification
- Identification of potential Use Errors, Hazards and Hazardous Situations
- Identification of hazard-related use scenarios and selection for Summative Evaluation
- Performance of Formative Evaluation and preparation of a Formative Report
- Performance of Summative Evaluation and preparation of a Summative Report
- Dealing with User Interfaces of Unknown Provenance (UOUP)

Risk Assessment

This section will look at the relationship between EN IEC 62366 and the Medical Device Risk Management Standard EN ISO 14971. The programme will also cover the implementation of risk assessment to ensure critical use-related risks are identified and reduced as far as possible.

Usability Guidance

The guidance and approach contained in the guidance documents from the MHRA and the US FDA will be discussed and the relationship between these documents and EN IEC 62366 will be explored.

Who should participate?

Engineer, Managers, Quality Professionals and other personnel in the Medical Device industry who need to gain a solid foundation in the principles and practices of Usability and Human Factors Engineering for Medical Device Software, Medical Device Hardware and Disposable Medical Devices

What will I learn?

Participants in this course will receive the knowledge to enable them to;

- Identify the EU regulations regarding Usability Engineering / Human Factors assessment
- Identify the steps involved in a Usability Engineering Process
- Identify the documents necessary for Usability Engineering for new and legacy products
- State the expectations regarding a Use Specification
- State expectations regarding;
    - Identification of potential Use Errors, Hazards and Hazardous Situations
    - Selecting hazard-related use scenarios for Summative Evaluation
    - Performance of Formative Evaluation and preparation of a Formative Report
    - Performance of Summative Evaluation and preparation of a Summative Report
    - Dealing with User Interfaces of Unknown Provenance (UOUP)
- State the relationship between EN IEC 62366, EN ISO 14971 and EN ISO 60601-1-6.

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.

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