SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

Validation of Software as a Medical Device and EN IEC 62304

LS045

Validation of Software as a Medical Device and EN IEC 62304

The main objectives of this course are to give attendees a good grounding in the principles of Medical Device Software Life Cycles Processes and Medical Device Software Validation. The course outlines the US and European regulations governing the development and validation of both Medical Device (SaMD) or Software in a Medical Device (SiMD). The course provides detailed training on the requirements of EN IEC 62304 with practical exercises covering the implementation of those requirements for SaMD and SiMD. The course materials include a full set of templates for implementation of the Medical Device Software Lifecycle. 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: 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?

Medical Device Software Regulations

The course covers the US requirements for the development of Software as a Medical Device and Software in a Medical Device and European requirements as outlined in EU MDR 2017/745 and EU IVDR 2017/746. The course goes on to demonstrate how to achieve compliance with these regulations through the implementation of EN IEC 62304 and related standards.

Contents of EN IEC 62304

The course will examine in detail the requirements for development, validation and maintenance of Medical Device software in accordance with EN IEC 62304. The course will cover the Software Development Process, The Software Maintenance Process, Software Risk Management, Configuration Management and the Software Problem Resolution Process.

The Software Development Life Cycle

The life cycle from design, through planning, development testing and maintenance for a medical device software project will be described with details on the contents of key documents / activities such as:

- Software Development Plans
- Software Classification
- Requirements Specification
- Software Specifications and Software Detailed Design
- Coding Standards and Code Reviews
- Dealing with Software of Unknown Provenance (SOUP)
- Software Unit Testing
- Integration and System Testing
- Software Maintenance Plans
- Software Problem Resolution
- End of Course Assessment

The Relationship to Design Controls

The relationship between EN IEC 62304 and the Design Control Requirements of 21 CFR part 820 and ISO 13485 will be discussed and methods of compliance outlined.

Risk Assessment

This section will look at the objectives for risk assessment, and will discuss the various standards such as ISO 14971 and IEC/TR 80002-1 and techniques involved and how these relate to EN IEC 62304. The programme will cover the implementation of risk assessment to ensure critical risks are identified and the correct level of validation is carried out.

Who should participate?

Engineers, Managers, Quality Professionals and other personnel in the Medical Device industry who need to gain a solid foundation in the principles and practices of Medical Device Software Development and Validation.

What will I learn?

Participants achieve the following learning outcomes from the programme;

- Apply the principles of Medical Device Software Development and Validation.
- Identify and generate the documents necessary to implement the Development/ Validation Life Cycle approach to Medical Device software.
- Implement requirements for software detailed design (where applicable).
- Implement requirements for software testing.
- Implement Requirements for SOUP.
- Implement software maintenance requirements.
- Apply Risk Management techniques to Medical Device Software Development and Validation.
- Apply the requirements for a software problem resolution process.

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.

Course Manual

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

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

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