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

This highly interactive two-day training course equips learners with the skills to apply EN IEC 62304 in a practical, structured way to achieve compliance. Delivered by expert tutors, the programme combines clear explanations of European and US regulations with hands-on exercises. The course covers 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. By the end of the training, learners understand how to plan, document and implement software lifecycle processes effectively.

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: 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?

The course content is organised into clear sections that build from regulatory foundations through to practical lifecycle activities.

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 examines in detail the requirements for development, validation and maintenance of Medical Device software in accordance with EN IEC 62304. The course covers the Software

Development Process, The Software Maintenance Process, Software Risk Management, Configuration Management and the Software Problem Resolution Process.

Risk Assessment

This section covers the objectives for risk assessment, and discusses 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 covers the implementation of risk assessment to ensure critical risks are identified and the correct level of validation is carried out.

The training involves practical exercises covering all the above topics, with learners encouraged to work on examples from their own workplace as part of these practical exercises. If required, content may be tailored to reflect your organisation's specific processes, risk profile and regulatory setting.

The Software Development Life Cycle

The software development life cycle, including planning, design, development, testing and maintenance, of a medical device software project are described with details on the contents of key documents and 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
- The Relationship to Design Controls

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

Who should participate?

This training is designed for professionals working in the medical device sector who are involved in Medical Device software development, quality assurance, compliance or validation. It is particularly beneficial for those who need a practical understanding of EN IEC 62304 and related regulations.

The training is particularly beneficial for:

- Software engineers, developers and project leads
- Quality and regulatory professionals
- Validation and risk management specialists
- Managers overseeing medical device software projects

Learners gain the practical knowledge and confidence necessary to ensure projects meet both European and US regulatory requirements.

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

What will I learn?

On successful completion of the training, learners will be able to:

- Apply the principles of Medical Device Software Development and Validation in compliance with EN IEC 62304
- Develop and maintain documentation across the full software development lifecycle
- Implement requirements for software design, testing and maintenance, including Software of Unknown Provenance (SOUP)
- Integrate software validation practices with risk management techniques in line with ISO 14971 and IEC/TR 80002-1
- Apply effective configuration management and problem resolution processes
- Relate EN IEC 62304 requirements to US 21 CFR 820 and ISO 13485 Design Controls

These outcomes ensure that learners return with the practical skills and knowledge necessary to deliver compliant medical device software development and validation projects within their organisations.

How will I be assessed?

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

- Checks understanding of the course content and practical scenarios
- Assesses practical understanding and application
- 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:

Support includes:

- Emphasis on hands-on application through practical exercises, case studies and group activities that reinforce key concepts and encourage active participation.
- Pre-training consultation for In-Company courses to tailor content to organisational needs
- Access to comprehensive course material that is regularly reviewed and updated to reflect the latest industry standards and guidance.
- Real time support from expert tutors

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

How can you progress?

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

- Software Validation (for Production and QMS applications)
- Medical Device Risk Management & ISO 14971
- Process Validation & Equipment Validation
- Process Validation for Medical Device Manufacturing
- Technical Writing Skills

These programmes build deeper expertise and provide complementary skills for advancing careers in medical device compliance and validation.

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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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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