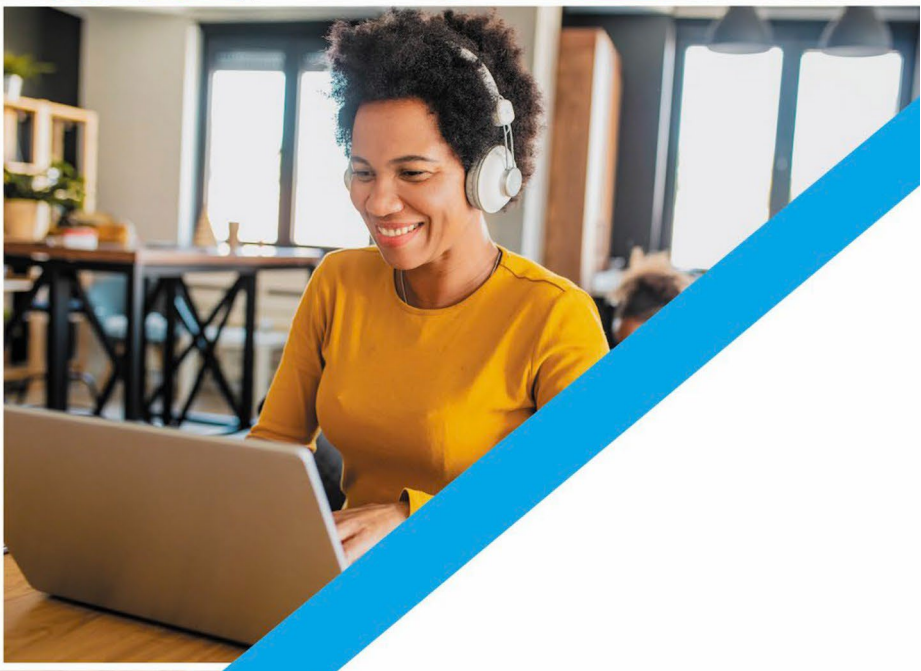
TRAINING THAT DEVELOPS
REAL CAPABILITY



QMS and Medical Device Software Validation

Three Day Training Programme

Course Title: QMS and Medical Device Software Validation

Duration: Three Days

Course Times: 9am to 4.30pm

Delivery: Virtual Classroom

Introduction

The main objectives of this course are to give attendees a good grounding in the requirements for Medical Device Software validation and Quality Management Systems (QMS) Software validation. The course will cover the implementation of those requirements through Software Validation and Medical Device Software Life Cycles Processes. The course will cover the applicable requirements from both the Europe and the US. The course will include practical exercises covering the implementation of those requirements.

What's covered?

Days 1 and 2: QMS Software Validation:

Regulations and Guidelines for Software Validation

The course will examine the regulations surrounding the current requirements for the validation of software and computer systems used in Manufacturing, Product Testing, Storage and Distribution, Quality Assurance and Regulatory Affair (known collectively in this document as QMS Software) both prospectively and retrospectively. Both FDA and EU regulatory guidelines will be discussed with regard to the Medical Device and Pharmaceutical industries. The use of the current GAMP 5 guidelines as a method of compliance with the regulations will be discussed.

The Software Validation Life Cycle

The V Model Software Validation life cycle from design, through construction, installation and live start-up for a typical software project will be described with details on the contents of key documents / activities such as;

- Master Validation Plan (MVP)
- User Requirement Specification (URS)
- Functional Design Specification (FDS)
- Design Qualification (DQ)
- Requirement Traceability matrix (RTM)
- Factory and Site Acceptance Testing (FAT and SAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Electronic Signatures and Records
This section of the course introduces the regulations governing the use of Electronic Records and Electronic Signatures in a regulated environment. Details of the requirements of 21 CFR 11 will be examined and the current expectations of the FDA with regard to implementation will be discussed.

Days 2 and 3: Medical Device Software Validation:
Risk Assessment
This section will cover the objectives of 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 the requirements for QMS Software Validation and the requirements of EN IEC 62304 Medical Devices Software Lifecycle Processes. The programme will cover the implementation of risk assessment to ensure that critical risks are identified and the appropriate level of validation is carried out.

Contents of EN IEC 62304
The course will cover in detail the requirements for development, validation and maintenance of Medical Device software in accordance with EN IEC 62304 Medical Devices Software Lifecycle Processes. The Design Control Requirements of 21 CFR Part 820 and how these apply to Medical Device Software will be covered in detail.

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

- Software Development Plans,
- Software Classification,
- Requirements Specification,
- Coding Standards and Code Reviews
- Dealing with S.O.U.P.1
- Unit Testing,
- Integration and System Testing,
- Software Maintenance Plans.

EN IEC 62366 Application of Usability Engineering to Medical Devices will also be discussed in relation to Medical Device Software and the fulfilment of EU and US requirements for Human Factors assessment. The relationship between IEC 62366, EN 14971 and EN IEC 62304 will be explained.

Participants will be given practical exercises to complete throughout the course to aid learning and develop practical validation skills.

Who Should Attend?

Developers of Medical Device Software, and IT, Engineering and Quality personnel who need to gain a foundation in the principles and practices of QMS and Medical Device Software Development and Validation.

What will I learn?

Participants achieve the following learning outcomes from the programme;

- Apply the principles of Software Validation to QMS Software.
- Implement the Validation Life Cycle and GAMP 5 approach to QMS Software
- Apply Quality Risk Management techniques.
- Generate key validation documents such as URS, FDS, VMP, IQ, OQ and PQ.
- Apply the requirements of 21 CFR part 11 in relation to Electronic Signatures & Records.
- Apply the principles of Medical Device Software Development and Validation.
- Identify the requirements of EN IEC 62304.
- Identify and generate the documents necessary to implement the Development/ Validation Life Cycle approach to Medical Device software.
- Implement Requirements for S.O.U.P.
- Implement software maintenance requirements.
- Implement software usability requirements.
- Write key validation requirements such as User Requirements and Test Cases.

Expert Course Tutors - Profile & Testimonials

John Lafferty

In-House Courses

For In-House courses, the tutor will contact you in advance to discuss the course programme in more detail in order to tailor it specifically for your organisation.

Course Manual

Delegates will receive comprehensive course resources.

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

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