SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY

Software Validation

LS035

Software Validation

Our fully interactive Software Validation training course provides attendees with the knowledge and skills they need to comply with European, US and Worldwide software validation requirements. The course is fully tutor-led and focuses on the practical implementation of software validation requirements. The course provides attendees with a well-thought-out approach and real-world implementation methodologies, to help achieve compliance and assure consistency of performance of computerised systems. The course addresses the use of software and computerised systems in QMS, production, testing and distribution. Risk Management of software and computerised systems, and scaling of validation effort in proportion to risk are covered in detail. The course also covers the latest FDA Requirements and Guidance on Electronic Records and Signatures (21 CFR Part 11) and Data Integrity. The course involves practical group exercises which take the learner through the entire validation cycle with comprehensive feedback from the course tutor throughout.

For abbreviations used in this document, see end of document.

Duration & Price

Duration: 3 days
Public Virtual Training: £890
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
30 Sep & 01-02 Oct 2025	Virtual	Book Date

In-Company Training

Please contact us for more information on our In-Company training options

What's covered?

DAY 1

- The Need for Software Validation
- European and FDA Regulations and Guidance on Software Validation
- Software Validation Regulations interactive quiz **New**
- The latest FDA Guidance on Software Validation **New**
- Group Discussion the latest FDA Guidance on software validation **New**
- The GAMP Approach to Software Validation
- GAMP Categorization case study **New**
- The V Model Approach
- V Model Approach interactive exercise
- Software Validation Planning - designing master validation plans
- Writing Software Validation Rationales **New**
- Case Study - determining what needs to be included in the MVP for a specific manufacturing process **New Content**

DAY 2

- Requirements Specifications - Case Study writing a URS
- Application of Risk Analysis to Software **Updated Content**
- Software Design Qualification
- Requirements Tracing – using the RTM to plan qualification testing
- Case Study - writing an equipment IQ Protocol
- Software Testing and Software Test Environments
- Software Testing Interactive Exercise
- Case Study - writing an equipment OQ Protocol
- Application of Statistics to Software Validation **New Content**
- Statistical Rationale for Samples Sizes **Updated Content**

DAY 3

- Electronic Records and Electronic Signatures
- 21 CFR Part 11 Interactive Exercise
- Application of the FDA Guidance on Part 11
- Data Integrity and Software Validation **New**
- Software Performance Qualification
- Case Study - writing a Software PQ Protocol **Updated Content**
- Leveraging Supplier documentation for off-the-shelf systems **Updated Content**
- Validation Reporting - How to Report on Software Validation testing **New**
- Maintaining the Validated State **Updated Content**
- End of Course Assessment. **New**

Who should participate?

Personnel in the Pharmaceutical/Medical Device/Healthcare sectors who need to gain a solid practical foundation in how to perform Computer Systems and Software Validation in a regulated environment.

What will I learn?

Upon completion of this course, participants will be able to;

- Identify the regulatory requirements for software validation,
- State the benefits of conducting software validation,
- Categorise software in accordance with GAMP guidelines,
- Apply the V Model to software validation,
- Appreciate European and FDA Guidance publications on software validation,
- Design a software validation master plan,
- Write user requirements for software and computerised systems,
- Assess software and computerised systems risks,
- Identify the main requirements for Electronic Records and Electronic Signatures,
- Apply the FDA guidance on 21 CFR Part 11 to software systems,
- State the main Data Integrity requirements,
- Complete a software DQ,
- Write IQ test cases for computerised systems,
- Identify challenge tests for software systems,
- Write Software OQ test cases,
- Write Software PQ test cases,
- Report on Software testing results,
- Leverage vendor documentation to minimise validation effort,
- Assist in ensuring that the validated state is maintained.

Abbreviations used in this document:

CPD: Continuous Professional Development
DQ: Design Qualification
GAMP: Good Automated Manufacturing Practice
IQ: Installation Qualification
MVP: Master Validation Plan
OQ: Operational Qualification
Part 11: 21 CFR Part 11 Electronic Records and Electronic Signatures
PQ: Performance Qualification
RTM: Requirements Traceability Matrix
URS: User Requirements Specification

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

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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SQT Training Ltd. | T: +353 61 339040 | E: info@sqt-training.com
W: sqt-training.com

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