SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY











Software Validation

LS035

Software Validation

This fully interactive three-day Software Validation training course provides attendees with the knowledge and skills they need to comply with European, US and Worldwide software validation requirements. Delivered by expert tutors, this highly practical course is designed to equip learners with a clear roadmap to plan, execute and maintain compliant validation activities for software and computerised systems used across QMS, Production, Testing and Distribution. The course is based on the latest FDA and GAMP guidelines and is designed to ensure that validation effort is proportional to risk and to eliminate unnecessary 'pro-forma' testing.

Throughout the course, learners engage in interactive group exercises and case studies that mirror industry specific scenarios, guiding them step-by-step through the full validation lifecycle. This hands-on approach ensures that concepts are clearly understood and internalised. Each exercise and case study is designed to reflect European, FDA and global regulatory expectations. As a result, learners are equipped to return to their workplace with the clarity, capability and confidence to implement robust, compliant validation practices that align with regulatory expectations and current best practice.

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.

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

Duration & Price

Duration: 3 days
Public Virtual Training: €1,055
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
02 - 04 Mar 2027	Virtual	Book Date

In-Company Training

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

What's covered?

This three-day programme combines interactive learning, case studies and group exercises to build validation skills across the software lifecycle through practical application and active participation.

Day 1

- The Need for Software Validation
- European and FDA Regulations and Guidance
- Software Validation Regulations Quiz
- The latest FDA Guidance on Software Validation
- The Computer Software Assurance (CSA) approach
- The GAMP Approach and Software Categorisation
- The V Model Approach to Software Validation
- Software Validation Planning
- Designing Master Validation Plans (MVP)

Day 2

- Writing User Requirements Specifications (URS)
- Risk Analysis of Software Applications
- Software Design Qualification (DQ)
- Preparing a Requirements Traceability Matrix (RTM)
- Writing IQ Protocols
- Software Testing and Test Environments
- Writing OQ Test Cases
- Applying Statistics to Validation
- Statistical Rationale for Sample Sizes

Day 3

- Electronic Records and Electronic Signatures
- 21 CFR Part 11 Compliance
- Data Integrity Principles and Practice
- Writing Software PQ Protocols
- Leveraging Supplier Documentation
- Validation Reporting and Maintaining the Validated State

The training involves practical exercises throughout covering all of 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.

Who should participate?

The training is particularly beneficial for those across the Medical Device, Pharmaceutical and Lifesciences sectors involved in:

- Validation of Software Systems
- Validation of Process Equipment or Test Equipment
- Ensuring Data Integrity and Part 11 Compliance
- IT in a regulated environment

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:

- Identify the regulatory requirements for software validation across Europe, the US and globally
- Apply the GAMP categorisation model to classify software systems appropriately
- Apply the latest FDA guidance (2025) and GAMP 5 edition 2 to implement validation activities in proportion to risk and to avoid unnecessary documentation and testing
- Implement the V-Model to structure validation activities and ensure traceability
- Design a software validation master plan
- Conduct a risk-based assessment to guide the level of validation effort required
- Write realistic and meaningful User Requirements Specifications (URS)
- Integrate Design Qualification (DQ) into the validation lifecycle
- Write software IQ, OQ and PQ protocols in line with the appropriate risk level
- Construct a Requirements Traceability Matrix (RTM)
- Execute software testing and interpret results aligned with statistical principles
- Apply 21 CFR Part 11 guidance and ensure Data Integrity compliance
- Leverage vendor-supplied documentation to reduce duplication of effort
- Develop and deliver validation reports that meet regulatory standards
- Define strategies for maintaining the validated state of computerised systems

These outcomes ensure learners return with practical skills and knowledge necessary to design, execute and sustain compliant software validation in a regulated environment.

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

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

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

How can you progress?

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

- 21 CFR Part 11 Electronic Records and Electronic Signatures and Data Integrity
- Process Validation & Equipment Validation
- Process Validation for Medical Device Manufacturing
- Validation of Software as a Medical Device and EN IEC 62304
- Medical Device Risk Management and ISO 14971:2019
- Pharmaceutical Quality Risk Management and ICH Q9
- Technical Writing Skills

Abbreviations Used in This Document

- CSA: Computer Software Assurance
- DQ: Design Qualification
- GAMP: Good Automated Manufacturing Practice
- ICH Q9: Guideline on Quality Risk Management
- 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

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

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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