SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY









Laboratory Software Validation

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Laboratory Software Validation

This fully interactive two-day Laboratory 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 in regulated laboratories in life sciences companies. The course is based on the latest FDA and GAMP guidelines designed to ensure that validation effort is proportional to risk and to eliminate unnecessary 'pro-forma' testing.

This course covers the validation of standalone software such as LIMS systems, statistical packages and databases as well software contained in laboratory equipment ranging in complexity from centrifuges to integrated HLPC systems. The course also covers the latest FDA Requirements and Guidance on Electronic Records and Signatures (21 CFR Part 11), Data Integrity and Quality Risk Management as applied to Laboratory equipment and software.

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 not only understood but internalised, with each exercise and case study designed to reflect European, FDA and global regulatory expectations. As a result, learners are equipped to return to their laboratories with the clarity, capability and confidence to implement robust, compliant validation practices.

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
Public Virtual Training: €745
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
11 - 12 May 2027	Virtual	Book Date

In-Company Training

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

What's covered?

This programme introduces learners to the full lifecycle of laboratory software validation, from planning and risk analysis through to maintaining the validated state. Case studies and

exercises reinforce each stage of the process.

Day 1

- The Need for Software Validation in the Laboratory
- European and FDA Regulations and Guidance
- Latest FDA Guidance on Software Validation
- Group discussion on new guidance
- The GAMP Approach
- The V Model
- Designing Master Validation Plans
- Writing User Requirements Specifications (URS)
- Applying Risk Analysis
- Software Design Qualification
- Requirements Tracing and RTM for testing

Day 2

- Writing an Equipment IQ Protocol
- Software Testing and Software Test Environments
- Interactive Software Testing Exercise
- Writing OQ Protocols
- Statistical Rationale for Sample Sizes
- Electronic Records and Electronic Signatures and 21 CFR Part 11
- Applying FDA Guidance on Part 11
- Data Integrity and Software Validation
- Writing Software and Laboratory PQ Protocols
- Leveraging Supplier Documentation
- Validation Reporting
- Maintaining the Validated State

The training involves practical exercises covering all relevant 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.

Abbreviations.

CFR - Code of Federal Regulation (US Federal Law)
GAMP - Good Automated Manufacturing Practice (Industry Guidance)
HLPC - High-performance Liquid Chromatography
IQ - Installation Qualification
LIMS - Laboratory Information Management Systems
MVP - Master Validation Plan
OQ - Operational Qualification
PQ - Performance Qualification
URS - User Requirements Specification

Who should participate?

This programme supports those responsible for laboratory software validation by providing proven methods, tools and exercises that build confidence and competence.

Suitable participants include:

- Laboratory Managers, Supervisors and Technicians
- Laboratory staff involved in the validation of laboratory systems, equipment and software
- IT personnel supporting laboratory systems

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 and interpret regulatory requirements for Laboratory Software Validation
- Categorise laboratory software in line with GAMP guidance
- Apply the V Model to software validation projects
- Design and implement a Master Validation Plan (MVP)
- Develop and assess User Requirements Specifications (URS)
- Evaluate risks using Quality Risk Management principles
- Apply FDA 21 CFR Part 11 requirements to electronic records and signatures
- Implement Data Integrity requirements
- Create and execute IQ, OQ and PQ test protocols
- Utilise vendor documentation effectively in validation activities
- Report effectively on software testing results
- Maintain the validated state of laboratory systems

These outcomes ensure that learners return with the practical skills and knowledge necessary to implement, manage and maintain compliant laboratory software systems.

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 personalised 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
- Technical Writing Skills

These pathways build on the foundational knowledge gained to further strengthen capability in validation and compliance.

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.



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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

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- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

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- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

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- Leadership & Personal Development
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