SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY

Laboratory Software Validation

L009

Laboratory Software Validation

Our fully interactive Laboratory Software Validation 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, providing attendees with a well-thought-out approach and real-world implementation methodologies to help achieve compliance and assure consistency of performance of computerised systems. 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) and Quality Risk Management as applied to Software Validation and Computer Systems Validation. 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 brochure, see end of brochure.

Duration & Price

Duration: 2 days
Public Virtual Training: €695
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
13 - 14 May 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 in the Laboratory
- European and FDA Regulations and Guidance on Laboratory Software Validation
- The latest FDA Guidance on Software Validation **New**
- Group Discussion the latest FDA Guidance on Software Validation **New**
- The GAMP Approach to Software Validation
- The V Model ApproachV Model Approach interactive exercise
- Software Validation Planning - designing Master Validation Plans
- 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

Day 2

- Case Study writing an equipment IQ Protocol
- Software Testing and Software Test Environments
- Software Testing Interactive Exercise
- Case Study writing an equipment OQ Protocol
- Statistical Rationale for Samples Sizes **Updated Content**
- 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?

- Laboratory Managers, Supervisors and Technicians who wish to increase their understanding of Laboratory Systems and Software Validation
- Laboratory Staff who will be involved in the validation of laboratory systems, equipment and software.
- IT personnel who will be involved in laboratory software valid

What will I learn?

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

- Identify the regulatory requirements for Laboratory Software Validation
- Categorise software in accordance with GAMP guidelines
- Apply the V Model to Laboratory 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
- Leverage vendor documentation to minimise validation effort
- Report on Software testing results
- Assist in ensuring that the validated state is maintained

How do we train and support you?

In-House Courses

Course tutor will contact your organisation in advance. In-house courses can be customised to meet your organisation's specific requirements. Where appropriate, course exercises can be carried out using procedures, data etc from your organisation.

Course Manual

Delegates will receive a very comprehensive course manual.

Acronyms used in this document.

CFR	Code of Federal Regulation (US Federal Law)
EU	European Union
FDA	Food and Drugs Administration
FDS	Functional Design Specification
GAMP	Good Automated Manufacturing Practice (Industry Guidance)
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IQ	Installation Qualification
LIMS	Laboratory Information Management Systems
OQ	Operational Qualification
PQ	Performance Qualification
URS	User Requirements Specification
MVP	Master Validation Plan

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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