SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY

Process Validation & Equipment Validation

LS034

Process Validation & Equipment Validation

Organisations must meet European, US and global validation standards, but many teams struggle to implement compliant and consistent validation systems. This highly practical three-day training course delivered by expert tutors covers every phase of process and equipment validation, equipping learners with the capabilities needed to meet EU, FDA and international compliance requirements with confidence.

Using a hands-on approach, the training focuses on the practical application of concepts such as equipment qualification, process validation, software integration, statistical sampling and ongoing compliance. Through interactive group exercises using practical examples, learners experience the full validation cycle from planning through to maintaining the validated state with proven methodologies to help achieve compliance and assure product quality and consistency.

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	
26 - 28 May 2026	Virtual	Book Date
01 - 03 Dec 2026	Virtual	Book Date

In-Company Training

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

What's covered?

Through interactive case studies and group exercises, this course explores each phase of the validation process, from initial planning through to ongoing compliance. Using the V Model, the modules are designed to ensure learners build step-by-step proficiency in applying validation principles in line with global regulatory requirements.

Day 1:

- Benefits of process validation
- EU and FDA validation regulations and guidance
- Validation planning and MVP design
- Validation vs. Verification (GHTF approach)
- Requirements Specifications (URS case study)

Day 2:

- Risk analysis application
- Equipment Design Qualification
- Requirement Tracing and RTM
- Equipment Qualification (IQ/OQ)
- Process control and capability
- Statistical rationale for sample sizes

Day 3:

- Process Performance Qualification (PPQ)
- Test method validation (including Gauge R&R)
- Continued Process Verification
- 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.

Who should participate?

This course is intended for anyone involved in the planning, execution, review or approval of process validations required to meet US or EU regulations, or anyone involved in the specification of process or test equipment for use in the life sciences industry.

The training is particularly beneficial for those involved in:

- Validation, Process and Equipment Engineering
- Production, Operations and Technical Services
- Quality Assurance and Regulatory Compliance
- Senior Management responsible for oversight, sign-off, or resource planning
- Members of Engineers Ireland seeking to claim CPD hours

This programme is Engineers Ireland CPD Approved

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 EU, FDA and international regulatory requirements for process validation
- Explain the key benefits and objectives of process validation activities
- Develop a validation master plan
- Write clear and structured User Requirements Specifications (URS)
- Conduct equipment and process risk assessments using standard tools
- Apply statistical approaches to sample size determination and process capability
- Prepare and execute IQ, OQ and PPQ protocols aligned to regulatory expectations
- Trace requirements through the validation lifecycle using tools like the RTM
- Validate physical test methods, including Gauge R&R and suitable alternatives
- Sustain the validated state through robust continued process verification

These outcomes ensure that learners return with the practical skills and knowledge necessary to validate reliable processes and meet regulatory requirements.

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 real-world 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:

- Software Validation
- Risk Management for Medical Devices (ISO 14971)
- Mastering CAPA in the Medical Device / Pharmaceutical Industry
- Technical Writing Skills

Abbreviations

- CAPA: Corrective and Preventive Action
- CPD: Continuous Professional Development
- GHTF: Global Harmonisation Task Force
- IQ: Installation Qualification
- MVP: Master Validation Plan
- OQ: Operational Qualification
- PPQ: Process Performance Qualification
- R&R: Repeatability and Reproducibility
- URS: User Requirements Specification

Tutors

Gerry Burke
View Profile

John Lafferty
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Kevina O’Donoghue
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Majella McEnroe
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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