SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY

Process Validation & Equipment Validation

LS034

Process Validation & Equipment Validation

Our fully interactive Process and Equipment Validation course provides attendees with the knowledge and skills they need to comply European, US and Worldwide validation requirements. The course is fully tutor-led and focuses on the practical implementation of validation requirements, providing attendees with a well-thought-out approach and real-world implementation methodologies to help achieve compliance and assure product quality and consistency. 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: €995
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
26 - 28 Nov 2024	Virtual	Book Date
27 - 29 May 2025	Virtua	Book Date

In-Company Training

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

What's covered?

DAY 1

- Benefits of Process Validation
- European and FDA Regulation and Guidance on process validation
- Validation Regulations interactive quiz **New**
- Validation Planning - designing master validation plans
- Writing Validation Rationales **New**
- Case Study - determining what needs to be included in the MVP for a specific manufacturing process **New Content**
- Validation versus Verification – implementing the GHTF approach
- Exercise on Validation versus Verification
- Requirements Specifications - Case Study writing a URS

DAY 2

- Application of Risk Analysis to Validation **New Updated Content**
- Equipment Design Qualification – comparing Specifications to Requirements
- Requirements Tracing – using the RTM to plan qualification testing
- Equipment Qualification
- Incorporating Software Validation into Equipment Validation **New**
- Process Optimization, Process Capability and Process Control **Updated Content**
- Case Study writing an equipment IQ Protocol
- Case Study writing an equipment OQ Protocol
- Application of Statistics to Validation **New Updated Content**
- Statistical Rationale for Samples Sizes **New Updated Content**

Day 3

- Process Performance Qualification
- Case Study writing a PPQ Protocol **New Updated Content**
- Product versus Process Validation
- Test Method Validation for physical test methods **New Updated Content**
- Gauge R&R and the alternatives to Gauge R&R
- Validation Reporting – How to present data and draw conclusions **New**
- Continued Process Verification
- Maintaining the Validated State **New Updated Content**
- End of Course Assessment. **New**

Who should participate?

- Personnel in the Medical Device, Pharmaceutical and API sectors who are engaged in validation activities.
- QA and Regulatory staff involved in auditing validation protocols and reports.
- Senior Management who need to allocate validation resources or review and approve validation programmes.
- Members of Engineers Ireland who attend this course may claim for CPD hours from Engineers Ireland.

What will I learn?

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

- Identify the regulatory requirements for process validation,
- Sate the benefits of conducting validation studies,
- Demonstrate an understanding of the key elements of process validation,
- Appreciate European and FDA Guidance publications on process validation,
- Determine where to use process capability and other statistical methods during validation studies,
- Demonstrate an understanding of the approach adopted by the GHTF regarding verification and validation,
- Design a validation master plan,
- Write requirements for process equipment,
- Assess process and equipment risks,
- Conduct equipment design reviews,
- Write IQ test cases,
- Write OQ test cases,
- Write PPQ test cases,
- Report on Validation testing results,
- Assist in ensuring that the validated state is maintained.

Abbreviations used in this document:

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

How do we train and support you?

In-House Courses

For In-House courses, the Tutor will contact the Course Organiser in advance to discuss the programme in more detail in order to tailor it specifically to the organisation.

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.

Tutors

Gerry Burke
View Profile

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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