SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

Process Validation for Medical Device Manufacturing - QQI Level 7

LS046V

Process Validation for Medical Device Manufacturing – QQI Level 7

This programme is specifically tailored for the medical device manufacturing sector. The goal is to empower learners with the necessary knowledge, skills, and proficiency to excel in a medical device manufacturing environment. By providing skilled validation practitioners, the programme helps medical device organisations meet industry demands effectively.

The programme is based on the regulations and the guidance documents applicable to medical devices and on current best practices within the industry. It incorporates multiple practical interactive exercises based on real-world examples. The assessment process centres around completing validation documentation based on a real-world validation project.

Benefits for the Learner

- Validation training with practical real-world medical device industry exercises.
- You will gain a QQI recognised Level 7 qualification in process validation.
- Boost your career with a Level 7 process Validation qualification.
- Learn to create validation documentation such as Validation Plans, URS, and IQ, OQ, and PQ protocols during the course.

Benefits for the Organisation

- Ensure validation staff are competent for roles through a QQI-accredited training programme.
- Prepare validation staff with practical training to minimise on-the-job training needs, freeing up managerial and engineering resources.
- Proficient personnel can improve validation approval rates and reduce validation lead times with accurate validation documentation.
- Investing in staff development improves retention rates as employees who feel valued are more likely to stay with the company.

Duration & Price

Duration: 6 days
Public Virtual Training: €2,495 + €350 fees
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
02-03 Sept, 22 Sept, 20 Oct & 28-29 Oct	Virtual	Book Date
21-22 Oct, 12 Nov, 09 Dec & 15-16 Dec	Virtual	Book Date
17-18 Nov, 08 Dec, 26 Jan & 02-03 Feb	Virtual	Book Date

In-Company Training

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

What's covered?

Validation Regulation and Planning

- Validation Regulations
- Validation Planning
- The GAMP Approach to Equipment Validation
- Generating Validation Master Plans

Risk Management for Validation

- Risk Management Requirements
- Preliminary Hazard Analysis (PHA)
- Failure Modes and Effects Analysis (FMEA)
- Application of Risk Management to validation
- Application of statistically valid sampling plans

Process and Equipment Design

- Writing a User Requirement Specifications (URS)
- Developing Equipment Specifications
- Performing Design Qualification (DQ)
- Process Design and Process Optimisation

Validation IQ and OQ

- Installation Qualification (IQ)
- Determining IQ tests
- Writing IQ protocols
- IQ Execution
- Operational Qualification (OQ)
- Worst-case Testing
- Writing OQ protocols
- OQ Execution and Reporting

Performance Qualification and Ongoing Control

- Process Performance Qualification (PPQ)
- Determining PPQ content and duration
- Writing PPQ protocols and reports
- Ongoing Process Control
- Maintaining the Validated State
- The Requirements Traceability Matrix (RTM)

Technical Writing Skills for Validation

- The Essentials of Good Communication
- Writing for the Audience
- Use of English
- Writing Rationales
- Writing Equivalence Statements

- The Introduction
- Validation Deviations
- The Validation Summary

Who should participate?

- Validation Engineers / Scientists currently working in the role who have no formal qualification in validation and may have learned through on-the-job training.
- Engineers/Scientists who are new to the medical device industry.
- Validation Technicians who wish to progress to a Validation Engineer role.
- Engineers, Scientists and Technicians working in the medical device industry who wish to transfer to a validation role.
- Quality, Regulatory and R&D professionals who wish to gain a thorough understanding of the expectations and practice of process and equipment validation or who wish to transfer to a validation role.
- Personnel not currently working in the medical devices industry, who wish to take up a validation or related role in the medical devices industry.
- Personnel who wish to gain a qualification in validation, in order to enhance their overall professional development.

What will I learn?

On successful completion of this programme, learners will be able to:-

- Identify the requirements of the regulations, standards and guidance governing process validation in the medical devices manufacturing industry.
- Apply the appropriate standards and guidance at each stage of the validation cycle.
- Evaluate the risks to patients and device users associated with each step of the manufacturing process under validation and determine how these risks can be addressed.
- Determine the validation tests required to demonstrate the acceptability of all identified process risks.
- Demonstrate the skills required to produce validation documents such as Validation Plans, Risk Assessments and IQ, OQ & PQ documentation to the standard required for compliance with medical device regulations.

What are the entry requirements?

Relevant qualification in an Engineering, Science or a related discipline at level 6 on the NFQ
OR
Two years experience working in a **technical** role in medical device manufacturing or a related industry or the engineering industry.
OR
Five years **general** experience working in medical device manufacturing or a related industry (e.g., Pharmaceuticals or Food).

English Language Requirements
For applicants whose first language is not English, SQT recommends a minimum English language competency of greater than or equal to B2+ in the Common European Framework of Reference for Languages (CEFRL) for successful completion of this programme. It is important to note that learners are not expected to have an IELTS or equivalent examination complete.

How will I be assessed?

Assessment consists of two written assignments as follows:

Assignment 1 - Weighting: 45%
Purpose: to demonstrate a knowledge of validation regulations and skills in producing Master Validation Plans, Risk Management and equipment and process design documentation.
Brief: Generate the following three documents for a given piece of equipment; a Validation Plan, a Preliminary Hazard Analysis and a Design Qualification Report

Assignment 2 - Weighting: 55%
Purpose: to demonstrate a knowledge of principles of Installation, Operational and Process Performance Qualification and demonstrate skills in producing IQ, OQ and PQ documentation.
Brief: Generate the following three documents for a given piece of equipment; Installation Qualification Protocol, Operational Qualification Protocol and a Process Performance Protocol

Both assignments are submitted in week 15 of the programme, a draft of Assignment 1 is submitted for review and feedback in week 7.

How do we train and support you?

Training Methdology

This Tutor-led training is delivered live via the virtual classroom using Zoom or MS Teams. Learner engagement is key to SQT's success. The training is highly interactive. You will be encouraged to keep your camera on, ask questions at any time and answer questions via your microphone or chat function. The programme is practically based, with real-life examples of validation best practice and group exercises using breakout rooms. All of our Tutors have worked in different aspects of validation prior to assuming their roles as validation trainers.

Assessment

Assessment is by means of two written assignments based on the generation of validation documentation. The assignments are designed to build on one another so the skills and learnings acquired in the first assignment can be applied to the second. You will be given the opportunity to submit the first assignment midway through the programme for review and feedback by the Tutor(s). General and one-to-one feedback will be given. You will also have the opportunity to communicate with the Tutor(s) throughout the programme should you need clarification or assistance with anything.

Access to Online Resources

SQT will provide you with access to a free online learning platform (Moodle). This platform provides you with access to a wealth of learning resources (such as course notes, presentations, additional reading, templates, screen casts and links to useful websites). You can also upload assessments and receive feedback from Tutors.

In-Company Courses

For companies running this programme In-House, the Lifesciences Programme Director will meet with the company in advance to determine how best the programme should be run in terms of scheduling and other company-specific needs.

Programme accreditation

This course is validated by QQI at Level 7 on the National Framework of Qualifications. Successful delegates will receive a Special Purpose Award, Certificate in Process Validation for Medical Device Manufacturing (10 ECTS Credits).

Awards made by QQI are on the National Framework of Qualifications (NFQ). The NFQ provides a way to compare qualifications, and to ensure that they are quality assured and recognised at home and abroad. Qualifications (awards) in the NFQ are recognised in Ireland and abroad.

How do I register for the programme?

Test text

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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