SQT TRAINING THAT DEVELOPS REAL CAPABILITY

Certificate in
Process Validation
for Medical Device Manufacturing

QQI - Level 7 - 10 Credits

6 Training Days

Live Delivery via Zoom

MORE INFORMATION :

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Why Choose this Course?

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.

Benefits for

The Learner

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

Benefits for

The Medical Device 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.

This course is the only accredited QQI qualification in Process Validation which is aimed exclusively at the Medical Device Industry.

Our Approach to the Programme

This programme provides you with the practical skills needed to specify process and equipment requirements and prepare the validation documentation necessary to ensure product safety and effectiveness, and meet regulatory requirements.

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.

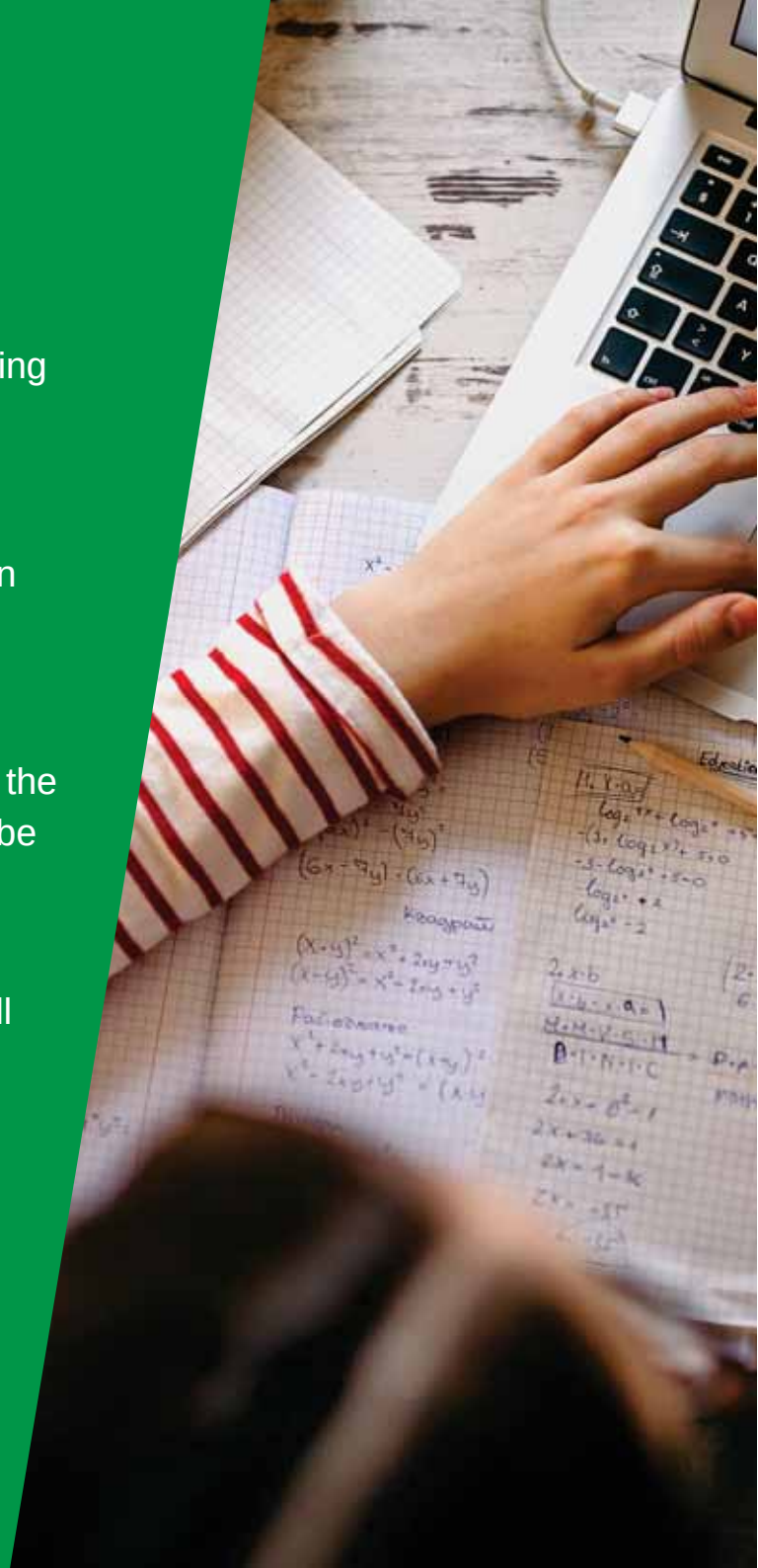
A key feature of the programme is the development of the technical writing skills necessary to produce validation documentation meeting the extremely high standards required within the medical device industry.

Learn about your company-specific processes
Bring validation examples from your own organisation to work on during the training.

What will I Learn?

On successful completion of this programme, you 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 is Covered?

Regulations and Validation 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

- 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

Training Timeline

This is a very practical, assignment-based programme. To ensure effective outcomes we complete the training elements over a number of weeks which allows you time to reflect on the content and apply it to your assignments.

Induction Session
1hr

Week 0

Week 1

Training
Day 1 & 2
Validation Regulation and Planning & Risk Management

Week 2

Training
Day 3 & 4
Process & Equipment Design, Technical Writing

Independent Learning: Use the course materials and multimedia resources to draft Assignment 1.

Draft of Assignment 1 to be submitted by Week 7 - Feedback provided by Week 9

Week 9

Training
Day 5 & 6
Validation IQ, OQ, PQ & Ongoing Control

Independent Learning: Use the resources provided to complete Assignments 1 and 2.

Week 15

Assignments 1 & 2 to be submitted by Week 15

In-Company Training - If you have a number of team members to be trained, we offer this programme in-company and can tailor the schedule to meet your particular business schedule.

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.

Engineers - Scientists - Technicians - Quality - Regulatory - R&D



Meet your Tutor

John Lafferty

Programme Director

John is a quality professional with over 25 years experience in the medical device and pharmaceutical industry. He joined SQT as a Tutor in 2007.

He has spent his entire career working in validation and quality roles within the medical devices / pharmaceutical sectors. John spent six years as Senior Manager of Quality and Regulatory Affairs in multinational medical devices manufacturing organisation.

John is a Lean Six Sigma Black Belt and derives great benefit from applying Six Sigma techniques to risk management and validation in a life sciences setting.

“It is great to be able to bring the knowledge and experience from ongoing involvement with life sciences companies into the classroom” he says.

What do John’s learners say?

"10/10 experience. I hope to receive more training from John and SQT in the future" Taylor R

"A great course, well delivered, with appropriate level of humour to keep the content from getting too 'heavy'" Jon S

“Very good delivery of content. Sparked great enthusiastic conversations and discussions on our current structures and requirements around validation. Helped identify areas we can improve on". - Mary F

How do we Train and Support you?

Training Methodology

- 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 and Assessment Support

- 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.

Free 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.

Company Support

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.

About this Qualification

On completing this course and successfully completing the assessment you will achieve the following certification:

Certificate in Process Validation for Medical Device Manufacturing

Level 7 - 10 Credits - Microcredential

QQI AWARD

National Framework of Qualifications

Qualifications (awards) on the NFQ are recognised in Ireland and abroad.

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.

Entry Requirements & Assessment

Entry Requirements:

- Relevant qualification in an Engineering, Science or a related discipline at level 6 or higher 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).

Attendance:

- Attend all 6 training days

Assessment:

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 Qualification Protocol.

To successfully pass the programme, learners need to attain a pass score (40%) in both assignments.

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For More Information contact us on

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We can schedule a call with John Lafftery our Programme Director if you would like to discuss the programme in more detail.