SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY

Pharmaceutical Equipment Qualification and Process Validation

LS050

Pharmaceutical Equipment Qualification and Process Validation

This highly interactive three-day training course covers every phase of pharmaceutical equipment qualification and process validation, equipping learners with the capabilities needed to meet EU GMP, FDA and international pharmaceutical compliance requirements. The programme reflects current pharmaceutical industry expectations for lifecycle validation and equipment qualification. Particular emphasis is placed on the principles outlined in FDA's Process Validation: General Principles and Practices guidance and EU GMP Annex 15, including; validation planning, equipment qualification, process design, process validation and maintaining the validated state throughout the product lifecycle.

Using a hands-on approach, the training focuses on the practical application of concepts such as equipment Design Qualification (DQ), Installation Qualification (IQ) and Operational Qualification (OQ), and Process Performance Qualification (PPQ), process control, and Continued Process Verification (CPV). Through interactive group exercises and pharmaceutical industry case studies, learners experience the full validation lifecycle from planning and qualification through to continued process verification and maintenance of the validated state, using proven methodologies to support regulatory compliance and assure product quality, safety and consistency.

We can customise 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

Coming Soon. Please contact us to receive notification of next Public Virtual Training Dates.

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 pharmaceutical validation, from initial planning through to continued process verification and lifecycle management. Using a lifecycle-based validation approach aligned with current pharmaceutical regulatory expectations, the training modules are designed to ensure learners build step-by-step proficiency in applying validation principles in accordance with global

regulatory requirements.

Day 1:

- Foundations of pharmaceutical process validation
- EU GMP Annex 15, FDA and international validation regulations and guidance
- Validation planning and Validation Master Plan (VMP) design
- Process validation lifecycle concept
    - Stage 1 Process Design
    - Stage 2 Process Qualification
    - Stage 3 Continued Process Verification
- Stage 1 Process Design
    - Quality by Design (QbD) principles and control strategy development
    - Quality Risk Management in pharmaceutical validation

Day 2:

- Stage 2 Process Qualification
- Stage 2.1 Equipment and facility qualification programme based on the Control Strategy
    - Equipment Design Qualification (DQ)
    - Equipment Qualification (IQ/OQ/PQ)
    - Requirements Traceability
- Stage 2.2 Process Performance Qualification (PPQ)
- Determining PPQ strategy
    - Grouping strategies (matrixing, bracketing, grouping)
    - Determination of number of Stage 2 PPQ batches
    - Application of statistical methods for sampling
- PPQ Readiness
- PPQ Documentation (plan, protocol, report)

Day 3:

- Process Performance Qualification (PPQ) Execution
- Stage 3 Continued Process Verification (CPV)
- Process control strategies and process capability
- Maintaining the validated state
- Revalidation strategies

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. Where requested, content can be customised to reflect your organisation’s specific processes, risk profile, and regulatory setting.

Who should participate?

This course is intended for anyone in the Pharmaceutical, Biopharmaceutical or API manufacturing industries involved in the planning, execution, review or approval of process validation activities required to meet EU GMP, FDA or international pharmaceutical regulations. It is also highly relevant to those involved in the specification, qualification and lifecycle management of manufacturing, utility, laboratory and automated systems.

The training is particularly beneficial for those involved in:

- Validation Engineering
- Process Development
- Process Validation
- Equipment Qualification
- Manufacturing Operations
- Production and Technical Services
- Quality Assurance
- Quality Control
- Regulatory Affairs
- Technical Operations
- Senior Management responsible for validation oversight, approval or resource planning
- Members of Engineers Ireland seeking to claim CPD hours

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 GMP, FDA and international pharmaceutical regulatory requirements for equipment qualification and process validation
- Explain the lifecycle approach to process validation throughout the product lifecycle
- Develop and maintain a Validation Master Plan (VMP)
- Understand the requirements for equipment, systems and utilities qualification.
- Apply risk-based approaches for determining validation strategy
- Apply statistical approaches to sample size determination and process capability
- Prepare and execute qualification and validation protocols aligned with regulatory expectations
- Implement effective Continued Process Verification programmes
- Maintain the validated state through lifecycle management and change control

These outcomes ensure that learners return to the workplace 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
- Helps to embed and reinforce the classroom learning
- Is completed within one week of course completion

Successful learners receive a Certificate of Achievement

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
- Pharmaceutical Quality Risk Management (ICH Q9)
- Mastering CAPA in the Pharmaceutical Industry
- Technical Writing Skills
- Pharmaceutical Quality Systems (ICH Q10)
- GMP Auditing
- API – Active Pharmaceutical Ingredients
- CAPA – Corrective and Preventive Action
- CPD – Continuous Professional Development
- CPV – Continued Process Verification
- DQ – Design Qualification
- FDA – Food and Drug Administration
- ICH – International Conference on Harmonisation
- IQ – Installation Qualification
- OQ – Operational Qualification
- PPQ – Process Performance Qualification
- QbD – Quality by Design
- VMP – Validation Master Plan

Tutors

John Lafferty
View Profile

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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