SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY









Test Method Validation

LS051

Test Method Validation

This highly interactive two-day training course provides a practical and structured approach to Test Method Validation (TMV) for physical test methods used in medical device and pharmaceutical manufacturing environments.

The course focuses on ensuring that test methods used to make quality decisions are reliable, repeatable and capable of producing valid results. Through a combination of tutor-led instruction, real industry examples and practical exercises, learners will gain a clear understanding of how to plan, execute, analyse and report on test method validations.

The training covers Gauge R&R and alternative approaches such as Precision to Tolerance, Gauge Capability and Analysis of Variance (ANOVA) for both destructive and non-destructive test methods. The training also covers Attribute Test Method Validation using Attribute Agreement Analysis. The training involves analysis of actual industry examples using statistical analysis software. The highly practical nature of this training gives learners the practical skills and confidence to complete test method validations that are fully compliant with regulatory expectations and industry best practice, allowing compliance with regulations and standards such as 21 CFR Parts 211 and 820, EU GMP Vol. 4, ISO 13485:2016 and ISO 11607.

Note: This course does not cover analytical test method validation (e.g. ICH/USP approaches). If your training need relates to validation of analytical test methods please enquire about our Analytical Test Method validation training programme.

We can customise the training to meet your specific training needs and incorporate your data and examples from your test methods into the training programme as required.

For abbreviations used in this document, see end of document.

Duration & Price

Duration: 2 days
Public Virtual Training: €745
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
04 - 05 May 2027	Virtual	Book Date

In-Company Training

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

What's covered?

Using practical examples, case studies and hands-on exercises, this course guides learners through the full Test Method Validation lifecycle, including planning, execution, statistical analysis and reporting.

The training includes:

Foundations of Test Method Validation

- Role of TMV in ensuring product quality and compliance
- Differences between validation of processes and validation of test methods
- Understanding attributes vs variables and the implications for test method validation
- Definition and objectives of Test Method Validation

Measurement Equipment Preparation

- Sources of variation: equipment, operator and sample variation
- Ensuring the suitability of the measurement system
- The need for equipment IQ/OQ
- The need for software validation
- Electronic Records and Data Integrity requirements

Variable Test Method Validation

- Gauge R&R principles and methodology
- Study design (sample selection, operators, repetitions)
- Interpretation of results (variation, % contribution, study variation)
- Acceptance criteria for Gauge R&R

Alternative TMV Approaches

- Precision-to-Tolerance (P/T) method
- Gauge Capability (Cg)
- Process-to-Tolerance concepts
- Validation through conformance to recognised standards

Attribute Test Method Validation

- Attribute Agreement Analysis
- Sampling approaches for attribute testing
- Establishing confidence in inspection decisions

Statistical Analysis and Use of Software

- Performing TMV analysis using statistical tools such as Minitab™
- Practical case study in the use of Minitab to perform Gauge R&R Studies
- Interpretation of graphical outputs and ANOVA tables
- Practical case study in the use of Minitab to perform Attribute Agreement Analysis
- Identifying measurement system issues

Protocols and Reporting

- Developing TMV protocols with defined acceptance criteria
- Executing studies in a controlled manner
- Documenting results and drawing valid conclusions
- Linking TMV to SOPs and quality systems

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 involved in the development, validation, execution or review of test methods used in life sciences manufacturing.

The training is particularly beneficial for those involved in:

- Validation Engineering and Quality Engineering
- Manufacturing and Production Operations
- Laboratory and Test Engineering (Physical test methods)
- Quality Assurance and Regulatory Compliance
- Technical Services and Process Support
- Research and Development

It is also suitable for managers responsible for approving validation strategies or ensuring compliance with regulatory expectations.

A good standard of written and spoken English is important to engage effectively with this programme.

Minitab™ software will be used throughout the training course. Delegates will need to have Minitab versions 20, 21 or 22.

A 14-day trial version of Minitab 22 software is available on www.minitab.com

What will I learn?

On successful completion of the training, learners will be able to:

- Explain the purpose and regulatory importance of Test Method Validation
- Differentiate between attribute and variable test methods and apply appropriate validation approaches
- Apply appropriate validation approaches for both destructive and non-destructive tests
- Identify and control sources of variation within measurement systems
- Ensure that equipment is suitable and prepared for the TMV study
- Develop clear, structured TMV protocols with appropriate acceptance criteria
- Run validation studies using appropriate blinding techniques
- Avoid common pitfalls when practically running a TMV study
- Design and execute Gauge R&R studies for variable data
- Apply alternative TMV approaches such as Precision-to-Tolerance, ANOVA and conformance to standards
- Analyse TMV data using statistical tools such as Minitab
- Perform Attribute Agreement Analysis for pass-fail based tests
- Analyse Attribute Agreement Analysis ouput using statistical tools such as Minitab
- Interpret TMV results and assess measurement system capability
- Produce validation reports that demonstrate regulatory compliance

These outcomes enable learners to confidently validate test methods and ensure that product quality decisions are based on reliable data.

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:

- Process Validation and Equipment Qualification
- Statistical Process Control
- Statistics with Minitab
- Software Validation
- Electronic Records & Electronic Records and Data Integrity
- Risk Management (ISO 14971 or ICH Q9)
- Technical Writing Skills

ATMV: Attribute Test Method Validation
ANOVA: Analysis of Variance

Cg: Gauge Capability Index
Gauge R&R: Gauge Repeatability and Reproducibility
IQ/OQ: Installation and Operational Qualification
MSA: Measurement System Analysis
P/T: Precision to Tolerance
QA: Quality Assurance
R&R: Repeatability and Reproducibility
SOP: Standard Operating Procedure
SPC: Statistical Process Control
TMV: Test Method Validation

Tutors



Grainne Heneghan
View Profile



John Lafferty
View Profile



Noel McCann
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

SQT Training Ltd. | T: +353 61 339040 | E: info@sqt-training.com
W: sqt-training.com

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