SQT

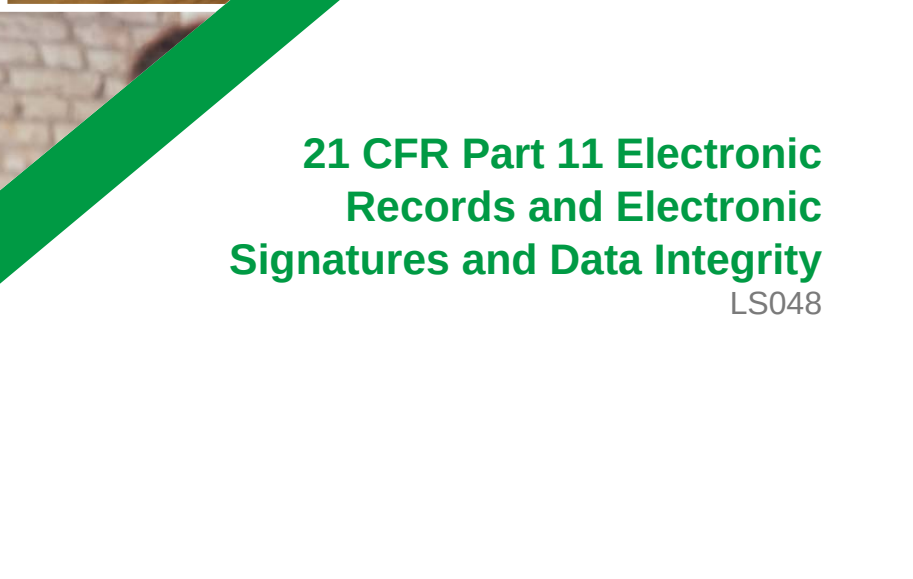
TRAINING THAT DEVELOPS *REAL* CAPABILITY











21 CFR Part 11 Electronic Records and Electronic Signatures and Data Integrity

LS048

21 CFR Part 11 Electronic Records and Electronic Signatures and Data Integrity

This highly interactive one-day training course gives attendees an excellent grounding in the principles and practices of Electronic Records and Electronic Signatures (ERES) and Data Integrity compliance. The course covers FDA and European requirements with practical exercises covering risk-based implementation of those requirements.

Delivered by expert tutors, the course covers 21 CFR Part 11, EU GMP Annex 11, and the FDA, WHO and MHRA guidance on data integrity. The training involves practical exercises focused on system validation, risk assessment and remediation strategies. Learners are equipped to return to their workplace with the clarity, capability and confidence to implement robust systems for compliance with ERES and Data Integrity requirements.

We can tailor the training to meet your specific training needs and incorporate examples from your processes and procedures into the training programme as required.

Duration & Price

Duration: 1 day
Delivery mode: This programme is available In-Company

Dates & Locations

In-Company training programmes are customised for your organisations specific needs. Most In-Company training is now delivered virtually.

In-Company Training

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

What's covered?

This course combines practical training with regulatory expertise to support effective implementation of 21 CFR Part 11, EU GMP Annex 11 and global Data Integrity standards.

Overview of 21 CFR Part 11 and EU GMP Annex 11
Covers core compliance obligations and regulatory definitions.

- Key concepts and definitions in 21 CFR Part 11 and EU Annex 11
- System types and processes under regulatory scope
- Differences between US and EU compliance expectations

Interpretation of FDA Guidance and enforcement expectations
Explains FDA enforcement discretion and system alignment.

- Current FDA guidance on 21 CFR Part 11
- Aligning legacy systems with expectations

- Documentation strategies for audit readiness

Practical ERES assessments and industry specific examples
Focuses on performing hands-on compliance assessments.

- ERES assessment tools and techniques
- Identifying gaps in real systems
- Planning mitigation strategies

ALCOA+ principles and lifecycle mapping
Explores data integrity through the ALCOA+ lens.

- ALCOA and ALCOA+ framework
- Mapping the data lifecycle
- Defining data control points

Data Integrity and risk assessments
Links data risk with validation and control decisions.

- Criticality and function, based risk assessments
- Risk-based controls and documentation
- Prioritised remediation planning

Validation approaches:
Details modern validation methodologies as outlined in the FDA CSV (2002), FDA CSA (2025), GAMP 5 Edition 2 (2022) guidance documents.

- CSV (Computerised System Validation vs CSA (Computer Software Assurance) principles
- GAMP 5 Edition 2 application
- Tailoring validation deliverables for High-Risk and Not-High-Risk software application

Strategies for remediation and system compliance
Outlines structured remediation for non-compliance.

- Common non-compliance issues
- Risk-based remediation roadmaps
- Compliant controls and documentation

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. If required, content may be tailored to reflect your organisation’s specific processes, risk profile and regulatory setting.

Who should participate?

This course equips learners with the essential skills needed to maintain compliance with 21 CFR Part 11, EU GMP Annex 11 and related frameworks.

The training is specifically tailored for professionals involved in GxP compliance and electronic recordkeeping, including:

- Quality Assurance and Compliance Officers
- Laboratory Managers and Analysts
- Manufacturing and Validation Engineers
- IT and System Administrators

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:

- Explain the key regulatory principles of Electronic Records and Electronic Signatures (ERES), including compliance obligations
- Define and apply the ALCOA+ principles to ensure data integrity across digital systems
- Interpret and implement the compliance requirements of 21 CFR Part 11 and EU GMP Annex 11
- Conduct effective Data Integrity and ERES assessments, including mapping data lifecycles and identifying Critical Data
- Use risk-based approaches for system validation and regulatory compliance
- Apply FDA, WHO and MHRA guidance on Data Integrity in the context of global data governance standards
- Develop targeted remediation strategies for legacy systems in regulated environments
- Create documentation for validation planning and regulatory requirements for new computerised systems

These outcomes ensure that learners return with the practical skills and knowledge to confidently assess systems, apply regulatory standards and support data integrity compliance effectively.

How do we train and support you?

SQT's training approach is practical, highly interactive and discussion-based, offering flexibility to meet each organisation’s specific needs.

- Pre-training consultation for In-Company courses to tailor content to organisational needs
- Emphasis on hands-on 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 virtual training or onsite delivery options to suit team requirements
- Real-time support from expert tutors during and after sessions

Class sizes are generally limited to 12–15 participants to support personalised learning and individual support, ensuring stronger retention and practical capability development.

How can you progress?

Learners who complete this course often continue to deepen their skills in:

- Software Validation
- Process Validation and Equipment Validation
- Process Validation for Medical Device Manufacturing
- Medical Device Risk Management and ISO 14971:2019
- Pharmaceutical Quality Risk Management and ICH Q9
- Technical Writing Skills
- Quality Management System Implementation

These programmes build upon the practical foundations established in this course.

Tutors



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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