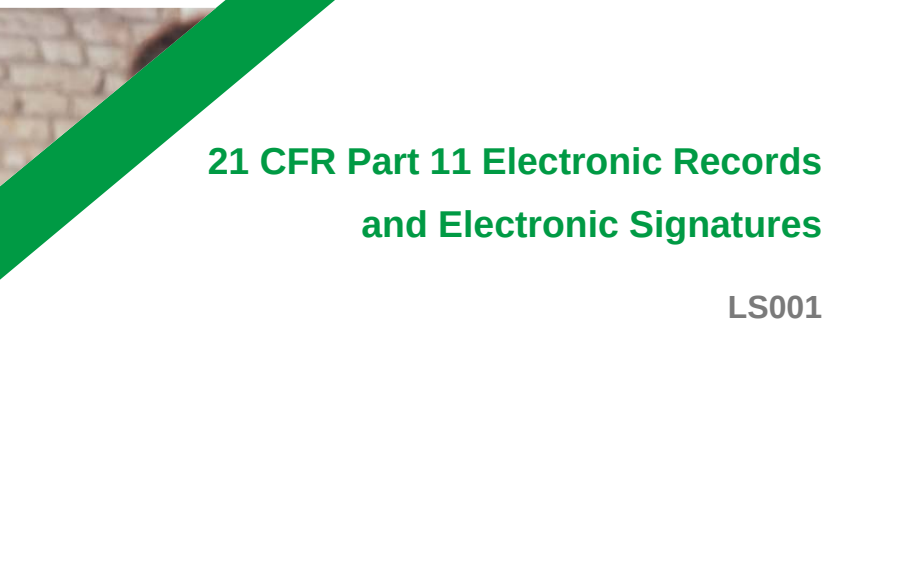
SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY



21 CFR Part 11 Electronic Records and Electronic Signatures

LS001

21 CFR Part 11 Electronic Records and Electronic Signatures

This programme is available In-House and currently delivered through virtual classroom training.

The main objectives of this course are to give attendees a grounding in the principles of and latest requirements for Electronic Records and Electronic Signatures (ERES). The course provides an overview of the FDA and European requirements with practical exercises covering the implementation of those requirements. The course covers the application of these requirements to both computer hardware and software systems used in Manufacturing, QA, Regulatory and the Control of Processes. The course also covers the latest FDA Guidance on Electronic Records and Signatures. Quality Risk Management as applied to Electronic Records and Signatures and validation of systems that use ERES are also addressed.

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?

Regulations for ERES

The course will cover in detail the requirements of 21 CFR Part 11, the US regulation covering Electronic Records and Electronic Signatures. What each clause of the regulation means and how it can best be complied with will be discussed and explained.

Guidance on 21 CFR Part 11

The FDA has issued detailed guidance on their expectations for the implementation of 21 CFR Part 11 and the level to which the regulation will be enforced. This course will explain this guidance in detail and propose a strategy for its application to both new and existing systems.

ERES Assessments

This section takes the participant through how an ERES assessment should be conducted and how the information gained from an ERES assessment should be used. It will involve practical examples that the participant can complete on the day, thus leaving them ready to complete ERES assessments once they return to their workplace.

Risk Assessment

The programme will cover the application of risk assessment to the management of Electronic Records and electronic signatures as required by 21 CFR Part 11 and the relevant guidance.

Validation

The programme will cover the validation of Computer Systems for Electronic Records and Electronic Signatures as required by 21 CFR Part 11 in line with GAMP 5.

Who should participate?

Personnel in the Pharmaceutical/Medical Device/Healthcare sectors who need to gain a solid foundation in the principles and practice of Electronic Records and Electronic Signatures in a regulated environment.

What will I learn?

Participants achieve the following learning outcomes from the programme;

- State the principles of Electronic Records and Electronic Signatures.
- Apply the requirements of 21 CFR Part 11 in relation to Electronic Signatures & Records.
- Apply Quality Risk Management techniques ERES.
- Conduct ERES assessments.
- Complete validation of Electronic Records and Electronics Signature applications.

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

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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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