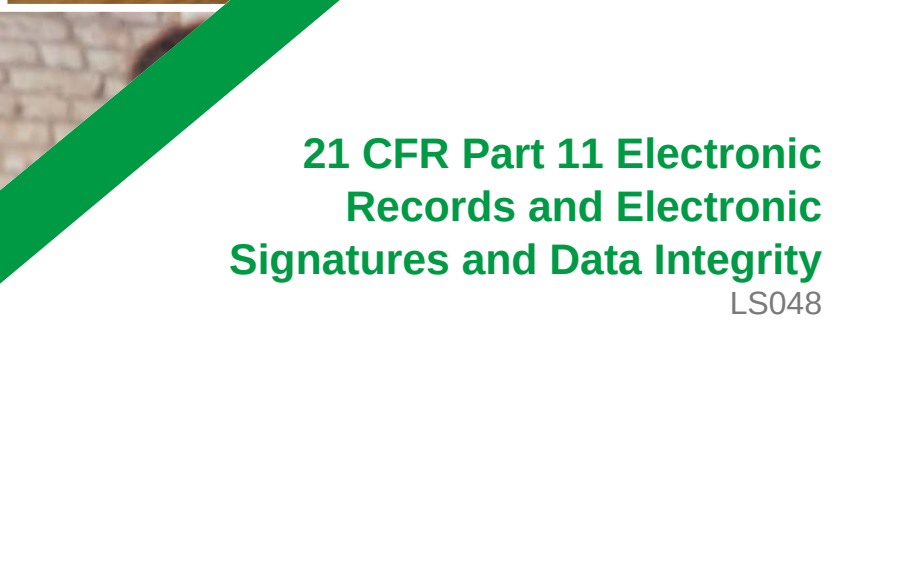
SQT

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 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 provides an overview of the FDA and European requirements with practical exercises covering the implementation of those requirements.

The course is fully tutor led and covers the application of these requirements to computer hardware and software systems used in Manufacturing, Laboratory Testing and Quality Management Systems. The course covers the latest FDA Guidance on Electronic Records and Signatures, and the FDA, WHO and MHRA guidance on Data Integrity.

The application of Quality Risk Management to Electronic Records and Signatures, and Data Integrity is also covered. Prior to the training course the tutor will contact you to discuss your training needs and to tailor the training to meet the exact learning objectives of your organisation.

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 covers, in detail, the requirements of the US 21 CFR Part 11 and European GMP Vol 4 Annex 11 regulations covering Electronic Records and Electronic Signatures. What each of the clauses of the regulations mean and the best means of compliance 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 participants can complete on the day, thus leaving them ready to complete ERES assessments once they return to their workplace.

Data Integrity

This training course covers the FDA, WHO and MHRA guidance documents on Data Integrity and the implementation in practice of the guidance given. The training will cover the “ALCOA-Plus” principles of Data Integrity and their application. The training will cover the identification of “Critical Data” and Mapping the Data Lifecycle. The training will cover Data Integrity Assessments and Validation for Data Integrity compliance - both described in more detail below.

Data Integrity and ERES Assessments

This section takes the participant through how a Data Integrity and ERES assessment should be conducted and how the information gained from the assessment should be used. It will involve working on practical examples from the attendees’ work-place.

Risk Assessment

The training covers the application of risk assessment to the management of Electronic Records and Electronic Signatures, and Data Integrity, to ensure that the compliance effort is in proportion to the risk involved with the underlying process and the use of the data.

Implementation and Validation

The training covers the validation of both new and existing computerised systems for Data Integrity and ERES compliance in line with the approaches outlined in; the FDA Guidance on Computerised Systems Validation - 2002 and Computer Software Assurance - 2022, and GAMP 5 Edition 2 - 2022. Approaches to remediation of existing systems is also covered.

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 and Data Integrity 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 compliance.
- State the ALCOA Plus principles of Data Integrity.
- Apply the requirements of 21 CFR Part 11 in relation to Electronic Signatures and Records.
- Apply the requirements of the requirements of EU GMPs Vol 4 Annex 11 in relation to Electronic Signatures and Records.
- Apply the FDA Guidance on Data Integrity and relate it to the requirements of 21 CFR Part 11.
- Apply WHO and MHRA Guidance on Data Integrity.
- Conduct Data Integrity and ERES assessments.
- Identify “Critical Data”
- Map the Data Process
- Document Data Integrity and ERES requirements for new computerises systems and software.
- Determine remediation and validation approaches for QMS, Manufacturing and Laboratory systems.

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.

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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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