SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY

Medical Device FDA QSR & QSIT

LS023

Medical Device FDA QSR & QSIT

Manufacturers of medical devices who intend to market their products in the USA are required to comply with the regulations set out in US FDA 21 CFR Part 820: Quality System Regulation. Failure to comply with any applicable provision of the QSR renders a device adulterated under section 501(h) of the Food, Drug and Cosmetic Act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

This course is designed not only to train participants in the QSR requirements, but to bring them fully up to date on the latest thinking and interpretations of the regulation using recent FDA warning letters and other information published by FDA. This course provides information on the Quality System Inspection Technique (QSIT) approach adopted by FDA inspectors when auditing Medical Device Manufacturers for compliance against the QSR.

This course brings compliance requirements to an understandable level. It uses discussion groups together with real life examples based on the tutors experience as a tool to ensure the learning is positive, fun and effective. Learners will receive the skills and awareness they need to implement their learning's within their own specific work environment in order to overcome their own specific challenges.

Duration & Price

Duration: 2 days
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?

Day 1

- Introduction to US FDA Quality System Regulation [QSR] : 21 CFR PART 820
- Medical Device FDA guidance documents
- An Introduction to QSIT
- QSR Subpart A - General Provisions, Subpart B - Quality System Requirements
- QSIT approach to auditing Management Controls
- Subpart C - Design Control
- QSIT approach to auditing Design Controls
- QSR Subpart D - Document Controls, Subpart E - Purchasing Controls & Subpart F - Identification & Traceability
- QSR Subpart G - Production and Process Controls
- QSIT approach to auditing Production & Process Controls

Day 2

- QSR Subpart H - Acceptance Activities, Subpart I - Nonconforming Product & Subpart J - Corrective and Preventive Action
- QSIT approach to auditing Corrective & Preventive action
- QSR Subpart K - Labelling and Packaging Control & Handling, Storage, Distribution & Installation
- QSR Subpart M – Records, Subpart N – Servicing & Subpart O - Statistical Techniques
- Preparing for an FDA Audit
- Medical Device Vigilance for Manufacturers

Who should participate?

- QA personnel responsible for the design and implementation of Quality Management Systems to comply with FDA QSR requirements
- QA personnel with responsibility for Quality Audit programmes
- Manufacturing & Process Engineers responsible for FDA QSR compliance
- R & D and Design Control personnel required to comply with FDA QSR
- Senior Management who need to demonstrate commitment to, and active participation in the Quality System.
- All personnel who are involved in quality management systems

What will I learn?

Participants achieve the following learning outcomes from the programme:

- Describe the FDA Quality System Regulation 21 CFR Part 820
- Understand the FDA audit approach following the Quality System Inspection Technique (QSIT)
- Appreciate the guidance documents provided by the FDA
- Gain an insight into recent FDA enforcement action

How do we train and support you?

In-House Courses

For In-House courses, the Tutor will contact the Course Organiser in advance to discuss the programme in more detail in order to tailor it specifically to the organisation.

Course Manual

Delegates will receive a very comprehensive course manual.

Tutors

John Lafferty
View Profile

Kevina O’Donoghue
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

Please follow us on social media for relevant news, events and updates