SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY

CAPA for the Medical Device Industry

LS031

CAPA for the Medical Device Industry

Our fully interactive Corrective and Preventive Action (CAPA) training course provides attendees with all the knowledge and skills they need to comply with the CAPA-related requirements of ISO 13485 and 21 CFR Part 820. The course is fully tutor led and focuses on the practical implementation of CAPA following the Seven CAPA Steps approach. The course focuses on real life situations from the workplace. The course involves practical exercises and group working with comprehensive feedback from the course tutor throughout, so that attendees can confidently implement CAPA requirements when they return to the workplace.

Duration & Price

Duration: 2 days
Public Virtual Training: €695
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
18 - 19 Feb 2025	Virtual	Book Date

In-Company Training

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

What's covered?

Implementing the Seven CAPA Steps

The course is based on seven easy-to-remember CAPA steps which when implemented will meet all of the European and US expectations for CAPA. A good CAPA system involves more than just taking action where failure has occurred; the Seven CAPA Steps provide a comprehensive approach to the implementation of a CAPA programme, from review of Quality trends through to the long-term assessment CAPA effectiveness.

CAPA Investigation

Inadequate investigation is one of the major causes of CAPA 483s at FDA inspections. This course demonstrates how to thoroughly document CAPA investigations to the FDAs satisfaction and gives delegates a toolbox of techniques that can be used to determine the root cause. Work completed during the course will allow the delegate to determine when to apply each tool for a given situation. ***New Root Cause Tools Added***

Root Cause Investigation Case Study ***New and Updated Content***

Correction, Corrective Action, Preventive Action *Updated Content*

This section of the course will help the delegate to determine the true difference between Correction, Corrective Action and Preventive Action.

The section covers;

- containment and a risk assessment of issues as they arise
- how to address systemic root causes
- how to implement real preventive measures such as potential failure analysis, standardisation and benchmarking.

Participants will complete practical work on a case study covering containment, risk assessment and CAPA actions. ***New and Updated Content***

CAPA Effectiveness *Updated Content*

Addressing CAPA effectiveness involves three distinct activities;

- verification or validation of the solution
- assessment of the long-term effectiveness of the corrective action
- monitoring the overall effectiveness of the CAPA system

This course provides the delegate with the knowledge and skills to implement the requirements pertaining to all three of these elements.

Case Study on CAPA Effectiveness ***New and Updated Content***

End of Course Assessment

This course now includes an end of course assessment. ***New***

Who should participate?

Personnel in the Medical Device manufacturing industry involved in any part of a CAPA system; these may include Operators, Technical Staff and Management from Production, Quality, Engineering or Support Functions.

What will I learn?

Participants achieve the following learning outcomes from the programme;

- Implement the Seven CAPA Steps approach.
- Meet FDA and European expectations when completing CAPAs.
- Conduct thorough Investigations into the causes of failure.
- Distinguish between Correction and Corrective Action.
- Distinguish between Corrective Action and Preventive Action.
- Generate Corrective Actions that truly address the Root Causes of failure.
- Write SMART Effectiveness Checks criteria.
- Assess the Effectiveness of Corrective Actions.
- Assess the Overall Effectiveness of a CAPA system.

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

Gerry Burke
View Profile

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

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