SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY









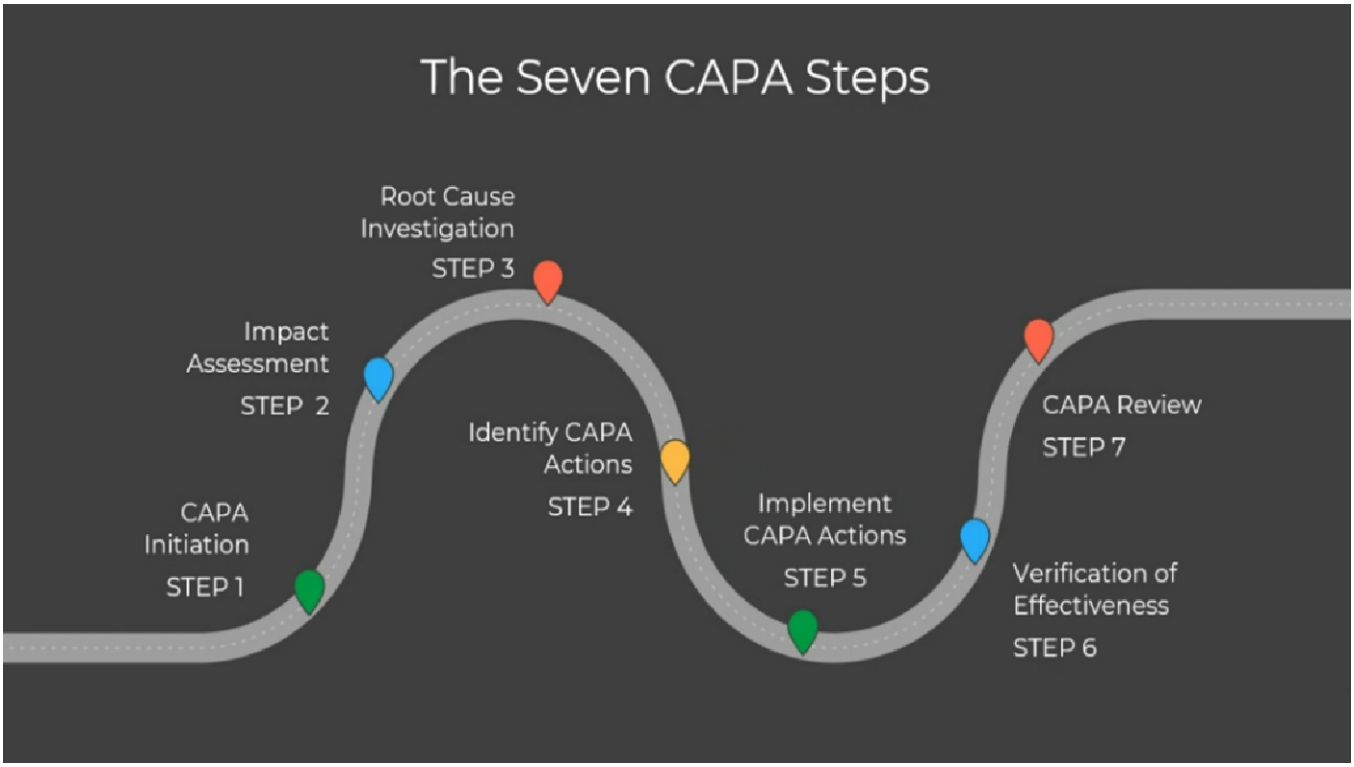


Mastering CAPA in the Medical Device Industry

LS031

Mastering CAPA in the Medical Device Industry

Ineffective CAPA is one of the most common findings resulting in 483 Observations issued by the FDA. This highly interactive, tutor-led course immerses learners in industry specific CAPA scenarios using collaborative case studies, breakout sessions and practical exercises, equipping them with the tools and confidence to meet the CAPA requirements of ISO 13485 and 21 CFR Part 820.



A good CAPA system involves more than just taking action when failure has occurred; the Seven CAPA Steps approach used in this training provides a comprehensive approach to implementing a CAPA system, from CAPA initiation right through to assessment of CAPA effectiveness. This training course equips learners to carry out thorough root cause investigations and to develop verifiable corrective actions using practical tools that they can readily apply in the workplace.

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: 2 days
Public Virtual Training: €745
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
22 - 23 Jun 2027	Virtual	Book Date

In-Company Training

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

What's covered?

This course is built around a structured Seven CAPA Steps framework, learners will engage in hands-on practical work through a detailed case study that reinforces key concepts and simulates industry specific CAPA challenges.

The key elements of the course are structured under the following areas of focus:

Implementing the Seven CAPA Steps

- Introduction to CAPA and regulatory expectations (ISO 13485 and 21 CFR 820)
- Overview and application of the Seven CAPA Steps
- Planning and documenting CAPA activities in alignment with compliance requirements

Root Cause Investigation

This section provides learners with a toolbox of techniques that can be used to effectively determine the root cause, these include Is/Is Not Analysis, Ishikawa Analysis, Concentration Diagrams, Control Charting, Cause Ranking, 5 Whys and many others.

- Root cause investigation tools, when and how to use them
- Documenting the Root Cause in an audit-ready format
- Hands on Root Cause investigation case study

Correction, Corrective Action and Preventive Action

True corrective actions prevent recurrence of quality issues; this training enables learners to focus on prevention rather than correction or detection.

- The differences between correction, corrective action and preventive action
- CAPA impact assessment and containment techniques
- How to implement true corrective actions using techniques such as Poka Yoke, potential failure analysis, standardisation and benchmarking
- Hands on case study covering containment, risk assessment and corrective actions.

CAPA Effectiveness

Addressing CAPA effectiveness involves three distinct activities, learners will practice all three;

- Validating the solution to ensure corrective actions address the original issue

- Assessing long-term effectiveness of the corrective action
- Monitoring the overall CAPA system to spot new or recurring problems

Learners will partake in a hands-on case study on CAPA effectiveness assessment.

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?

Organisations rely on diverse teams to maintain quality standards. This course equips personnel from a variety of disciplines with skills needed to implement CAPA successfully.

The training is particularly beneficial for those involved in:

- Quality Assurance and Regulatory Affairs
- Manufacturing, Production or Operations
- Engineering and Technical Support
- Internal Auditing or Compliance Management

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:

- Apply the Seven CAPA Steps methodology to meet EU and FDA expectations
- Differentiate clearly between correction, corrective action and preventive action
- Conduct structured investigations and identify true root causes
- Design CAPA actions that address systemic quality issues
- Develop and implement SMART effectiveness checks
- Evaluate both individual corrective actions and overall CAPA system performance

These outcomes ensure that learners return to the workplace with all the practical skills they need in order to confidently complete effective CAPAs.

How will I be assessed?

To consolidate learning and reinforce key concepts, learners complete a **post-course** assessment.

The assessment;

- Checks understanding of the course content and practical scenarios
- Assesses practical understanding and application
- Is completed within one week of course completion

Successful learners receive a Certificate of Achievement, in addition to their Certificate of Attendance

How do we train and support you?

Our training methodology is highly interactive, combining theory with application to build confidence and capability. Learners participate in structured discussions, case studies and applied activities throughout the programme.

Our support includes:

- Emphasis on hands-on application through practical exercises, case studies and group activities that reinforce key concepts and encourage active participation
- Pre-training consultation for In-Company courses to tailor content to organisational needs
- Access to comprehensive course material that is regularly reviewed and updated to reflect the latest industry standards and guidance.
- Flexible delivery options to suit different needs:
- Onsite or live virtual sessions tailored for teams
- Scheduled virtual public courses for individual learners
- Real-time support from expert Tutors

Class sizes are generally limited to 12-15 to support personalized learning and individual support.

How can you progress?

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

- Technical Writing Skills for Deviations and Investigations
- Quality Risk Management & ICH Q9
- Process and Equipment Validation
- MDSAP Internal Quality Auditor
- ISO 13485:2016 & The Medical Devices Regulation (CE Marking Process)

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

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