SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY

CAPA for the Pharmaceutical Industry

LS003

CAPA for the Pharmaceutical Industry

Corrective and Preventive Action (CAPA) continues to be one of the top two causes of 483s from the FDA. One of the main causes of companies receiving a CAPA 483 from the FDA is failure by the company to fully understand the FDA's expectations of a well run CAPA system. This course provides delegates with a comprehensive understanding of the FDAs expectations while also covering the European requirements for CAPA in full.

By attending this course delegates will obtain the tools and skills necessary to implement a CAPA system that not alone meets FDA and European requirements, but also brings about real improvement in the company's product and Quality System performance. Practical exercises will be completed throughout the day covering real life situations so that delegates can be confident of implementing CAPA requirements to the FDA's satisfaction when they return to the workplace.

The course covers the Seven CAPA Steps approach to fulfilling the CAPA related requirements of 21 CFR part 211, ICH Q10 and, FDA and European Guidance Documents.

Duration & Price

Duration: 1 day
Course Times: 9.00am - 5.00pm. Time Zone: Europe - Dublin

Delivery mode: This programme is available In-Company

In-Company Training

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

What's covered?

The Seven CAPA Steps

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

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.

Correction, Corrective Action, Preventive Action

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, standardization and benchmarking.

Assessing CAPA Effectiveness

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.

Who should participate?

Personnel in the Pharmaceutical 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 Learner's Say

‘The course was great, our tutor (John Lafferty) was very good in getting everyone to interact and take part making it very worthwhile’.

Niamh Foley, d?TERRA

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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