SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY













Internal Quality Auditing for Manufacturers of Active Pharmaceuticals Ingredients

LS017

Internal Quality Auditing for Manufacturers of Active Pharmaceuticals Ingredients

This programme is available In-House and currently delivered through virtual classroom training.

Internal auditing is fundamental to any quality improvement initiative. In particular, the FDA cGMP's for Pharmaceutical Products require that an organisation conduct internal quality audits to determine the effectiveness of its quality system. EU GMP requirements expect that companies conduct self inspections. Trained auditors must carry out these audits.

Thousands of internal audits are performed each year providing little internal business benefit. This course focuses on auditing company quality systems for real quality improvement rather than just compliance.

This two day course provides detailed training in developing the skills necessary to be an effective internal auditor.

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?

Please Note: A practical audit within the company forms the basis of day 2. Audit areas within the company must be organised prior to the training so that effective preparation can commence on day 1. For this reason the numbers on this course are restricted to max 12 (4 audit groups of 3) to ensure all delegates get the attention needed to ensure they become effective Auditors.

Day 1

- Introduction to Quality Systems
- Purpose of Internal Quality Audits
- The Audit Process
- Selecting the Audit Team
- Tools available to Auditors
- Audit Preparation
- FDA CFR part 211 cGMP for Pharmaceuticals & additional EU GMP Part II requirements

Day 2:

- Audit Preparation (Follow on from Day 1)
- Audit Performance
- Evaluating & Reporting the Audit

Delegates must attend both days to receive a Certificate of Attendance.

Who should participate?

- Any person in the organisation with responsibility for conducting internal audits
- Departmental managers and supervisory staff
- Quality Managers, quality engineers and supervisory staff
- Staff with responsibility for designing and implementing quality systems
- Personnel responsible for supplier / external audits.

What will I learn?

Participants achieve the following learning outcomes from the programme;

- Understand the requirements of the FDA CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals & EU GMP Part II requirements
- Understand the importance of internal auditing within a quality management system
- Understand the responsibilities of Internal Auditors
- Conduct an effective internal audit e.g. plan and organise an internal audit against the organisation’s documented procedures
- Collect and analyse evidence objectively
- Evaluate and report the results of an internal audit

Tutors



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.



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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

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- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

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- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

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