









**Technical Writing Skills for Deviations and Investigations** 

LS043

## **Technical Writing Skills for Deviations and Investigations**

Good quality investigation and deviation reports are vital for the achievement of effective corrective actions to address issues that arise in production or within the laboratory. When writing investigation and deviation reports it is also vital to demonstrate that the Quality System remains in a state of control and that the product remains safe and effective. Despite well-intentioned effort, technical personnel often fail to meet these challenges due to poor, communication and writing skills.

Attending this comprehensive training course will help technical personnel to get the message across clearly and will save them time during the report approval process. Our structured, practical programme will help attendees to identify the key message and to deliver it clearly and concisely in a way that displays compliance with applicable regulations. The course features writing practice and feedback throughout, to allow attendees to hone their writing skills during the course.

Abbreviations used:

CAPA: Corrective and Preventive Action

RCA: Root Cause Analysis

#### **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?

#### **Module 1: Writing for the Audience**

- Writing for the audience.
- · Getting the message across.
- The Outside-In approach.
- · Word choices and editing.
- Do's and Don'ts of Writing for the Auditor.

#### Module 2: Writing Problem Statements

- Stating the issue from the Outside-In.
- Identifying the What, Where, When, Who and How of the issue.
- Giving each of the above the prominence it deserves.
- Communicating the risk associated with the issue.
- Documenting containment actions.
- Viewing the problem through the eyes of the auditor.

#### **Module 3: Defining the Root Cause**

- Writing Root Causes based on RCA tools such as Fishbone and 5 Whys.
- Documenting the investigation.
- Presenting the information using a logical flow.
- Writing the rationale for the root cause.
- Documenting the rationale for the exclusion of potential root cause candidates found not to be part of the actual root cause.

#### **Module 4: Identifying Verifiable Corrective Actions**

- Identifying corrective actions that address the root cause not the symptoms.
- Identifying corrective actions that are implementable.
- Establishing how the effectiveness of the corrective action will be verified.
- Documenting corrective actions that are verifiable.
- The Investigation Summary.

#### Module 5: Applying the Learning to Other Documents

- How to apply the learning points form the course to other documents such as;
  - Change Controls
  - Memos
  - Procedures and Work Instructions
  - Issuing instructions and the use of the imperative.

The programme will be built around the client's examples and requirements, and will feature practical exercises to help learners hone their skills during the course.

At the end of the course each participant is asked to prioritise a personal list of learning points and to commit to implement these when writing deviations or investigation reports.

## Who should participate?

Any technical personnel involved in writing deviations or investigation reports.

#### What will I learn?

On completing this course participants will be able to:

- Analyse the audience and write documents with the readers' aims in mind.
- Write measurable Problem Statements
- Document actionable Root Causes
- Write realistic Containment Actions
- Document verifiable Corrective Actions

## What are the entry requirements?

For applicants whose first language is not English, SQT recommends a minimum English language competency of IELTS 6.0 (or equivalent) for successful completion of this programme. It is important to note that learners are not expected to have an IELTS or equivalent examination complete. Potential delegates are expected to <u>self-assess</u> their English language competency against the IELTS Band scores which can be found in <u>this</u> document.

# How do we train and support you?

#### **In-House Courses**

Course tutor will contact your organisation in advance to discuss the programme in detail. In-house courses can be customised to meet your organisation's specific requirements.

#### **Course Manual**

Delegates will receive a comprehensive course manual with relevant course materials.

# **Tutors**



**Gerry Burke**View Profile



**Ita Lafferty**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 <a href="CourseCheck.com">CourseCheck.com</a>, 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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