

Advanced Technical Writing for the Manufacturing Sector

The Advanced Technical Writing programme is designed to provide learners with the competencies and knowledge to consistently create high quality content for a regulated environment.

Participants will be introduced to the importance of data integrity and preparing documentation for auditors. Learners will also gain essential skills to support root cause analysis and corrective / preventative action investigations (CAPA), providing effective reports with a systematic and organised approach.

Aims and Objectives

This programme aims to establish a high standard of technical writing within manufacturing organisations. On completion of this programme learners will be to develop documentation which is factual, coherent, succinct, and readable for an intended audience. The course will incorporate key concepts such as corrective and preventative actions (CAPA), deviations and root cause analysis.

Learning Outcomes

On completion of this programme the learner should be able to:

- Demonstrate the ability to develop effective technical documents for a defined target audience
- Apply ALCOA (Attributable, Legible, Contemporaneous, Original, and Accurate) principles and understand the importance of data integrity
- Ensure all information documented presents with a logical flow and is chronologically organised

PROGRAMME DELIVERY

1 day online delivery.

PROGRAMME CERTIFICATION

Innopharma Education Certificate of Completion & AMTCE Digital Badge.

WHO IS THIS PROGRAMME FOR?

This programme is aimed at employees in all manufacturing sectors wishing to upskill in the area of Technical Writing.

ENTRY REQUIREMENT

To be eligible for this programme you must be in current employment.

CHANGE DIRECTION, ADVANCE YOUR CAREER

- Apply a consistent approach to the structuring of documents and reports
- Demonstrate the ability to write with focus and present information in a clear and concise manner
- Demonstrate an awareness of root cause analysis methodology and CAPA documentation

Course Content

- Definition of Technical Writing, Good Documentation Practices and regulatory requirements
- ALCOA principles, the importance of data integrity and the challenges faced when developing high standard manufacturing documentation
- Characteristics of effective technical writing and document design, templates, layout, language and standardisation
- The importance of audience recognition and writing for auditors
- Technical writing skills required when documenting CAPA investigations and root cause analysis

Other courses options include

- Introduction to Technical Writing for the Manufacturing Sector
- Introduction to cGMP for the Bio-Pharmaceutical Industry
- Introduction to Clinical Trials for the Pharmaceutical Sector
- Introduction to Validation for the Pharmaceutical Sector
- Introduction to Quality Control for Bio-Pharmaceutical Manufacturing
- Certificate in Supply Chain (Special Purpose Award/QQI Level 6 20 credits)
- Certificate in Operational Excellence (Special Purpose Award/QQI Level 6 25 credits)

A PROFILE OF IRELAND'S ADVANCED MANUFACTURING SECTOR

Advanced Manufacturing accounts for

36.7%

of GDP in Ireland

The sector employs

231,000

direct employees

9

out of the world's top 10 STEM companies have a presence in Ireland

Ireland is the world's

3rd

largest exporter of pharmaceuticals

Ireland's life sciences sector has a **global reputation** for operational and innovation excellence

For more information on this course contact Pauline Flusk (Programme Lead) on: T: +353 (0) 1 264 5570
e-mail: fluskp@innopharmalabs.com Visit our website on www.innopharmaeducation.com