COBBLESTONE

Effective and Compliant Technical Writing

DIRECTED BY

Joy McElroy — Validation Manager in the Regulated Industry

2.5 HOUR

ACCREDITED COURSE

Course Topics Include:

- Narrative and technical differences
- Types of technical writing examples
- Assess and write to the audience
- Know how to review and revise documents
- Understand your own writing patterns and know the answers to your questions about the English language

about the course

This technical writing training program will offer you an understanding of how the reporting process supports products in research, development, and in the marketplace. This 2.5-hour, accredited training will highlight the mandates for documentation set forth by the regulators, such as the FDA, the ISO, and other governing bodies. The program will train you on effectively reviewing and revising documents and assessing your audience, thus, producing effective written correspondence.

who should attend

This course is geared toward the industries of Pharmaceutics, Biologics and Medical Device Manufacturing. It is intended for professionals in Analytics, Operations, and Managerial roles. It would be beneficial to those who work in departments such as:

• Quality Assurance	• Quality Control
• Manufacturing	• Engineering
• Documentation	

For information on pricing, terms/conditions, Team Training, and other courses, please visit **www.TrainwithCobblestone.com**

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learning objectives

This course will address how to write effective correspondence and reports in support of your company's activities. You will learn how to organize and deliver information to the intended audience. You will also learn how to write clear and readable documents, and how to revise and refine your own and others' writing. The course will provide an overview of sound grammatical conventions, address problematic areas of the English language, and afford opportunities to address specific language issues.

Upon completion of this course, you will be able to:

- Interpret mandates for documentation set forth by regulators
- Apply the reporting process to support qualification, and validation protocol execution reporting
- Use properly worded documents from concept to final study report
- Produce effective written correspondence
- Assess and write to the audience
- Organize, structure, and deliver sound reports
- Compose grammatically correct passages with proper punctuation and voice
- Review and revise documents
- Discover your own writing patterns and increase writing confidence

course outline

Review of Learning Objectives
Module 1: What is Technical Writing? How is it different from Narrative Writing?

- Foundation
- Competencies
- Narrative and technical differences
- Types of technical writing examples

Module 2: Effective and Organized Technical Writing

- Produce effective written correspondence
- Assess and write to the audience
- Organize and deliver information based on the message
- Create grammatically sound passages
- Understand how active and passive voices work and how to choose
- the most appropriate one for the type of writing

Module 3: Writing Patterns and Previous Knowledge

- Review of proper use of punctuation marks and their role in making documents readable
- Know how to review and revise documents
- Understand your own writing patterns and know the answers to your questions about the English language
- Summary

Question and Answer Session
Assessment Opportunity

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course instructor

Joy McElroy earned a Bachelor of Science degree in Zoology at North Carolina State University. She began working in the pharmaceutical and biologics industries in 1992 at Pharmacia & UpJohn performing Environmental Monitoring and Sterility Testing. She then moved into a supervisory role at Abbott Laboratories where she oversaw the Quality Control Lab. In 1998 Joy moved to Wyeth Lederle and worked in Quality Assurance, performing GMP Compliance audits, batch record reviews, and holding annual GMP training for new employees. After working in Quality Assurance for a few years, Joy moved into Equipment Qualification and Cleaning Validation at Mallinckrodt. With 28 years total experience in the pharmaceutical and biologics industries, Joy has gained extensive knowledge of Quality Assurance, Technical Writing, Process and Cleaning Validation, Equipment Qualification, Computer System Validation and Part 11 Compliance. She has written and executed validation protocols and equipment qualifications for numerous companies such as Mallinckrodt, Wyeth Lederle, Merck, BioMerieux, Catalent, Biotest, Novartis, Imprimis, Cody Laboratories, and Xceilence.

Joy specializes in Equipment Qualifications, Cleaning and Process Validations, GMP Compliance Auditing, Technical Writing, and Training within the Pharmaceutical and Biologics manufacturing industries.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .3 CEUs. For further information, visit www.iacet.org

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