COBBLESTONE

COURSE ID 0162

Writing Effective Regulatory, Medical and Technical Documents

DIRECTED BY

Zeinab Schwen, President, Strategic Regulatory Consulting

12 Hours

ACCREDITED COURSE

- Regulations and Ethical Responsibilities
- Crafting Effective Messages
- Writing Concisely & Accurately
- Enhancing Your Editing Skills
- Building Quality Documentation

about the course

The success of a company's drug product or medical device regulatory submission is heavily dependent on the quality of its documentation submitted to regulatory authorities. Therefore, crafting precise, concise, well-referenced, and unambiguous technical documents is vital for business success. To produce such high-quality documents, effective writing skills must be continually honed.

In this 12-hour practical and accredited course, you will acquire techniques to assess your writing style and implement strategies for presenting complex ideas in a clear and concise manner. Through a blend of lectures and class exercises, you will learn methods for structuring, writing, revising, and proofreading documents and correspondences. Additionally, the course will cover critical components of technical report sections and provide guidance on writing effective summaries and responding to FDA requests for information.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer as well as a microphone and speakers/headset to fully participate.

who should attend

This course will benefit professionals from new hires to managers in the pharmaceutical, medical device, biologics and related health industries who would like to write more effective documents. It is a valuable course for those in:

- Clinical Research
- Regulatory
- Manufacturing
- Directors and Managers
- Compliance
- Product Development
- QA/QC
- Engineering/Scientists
- New Hires

Individuals who assess the readiness of documents for submission would also benefit from this course to better provide feedback to authors on needed revisions.

learning objectives

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

- Describe your role as a writer and your ethical responsibilities
- List the regulations controlling quality documentation
- Evaluate your writing patterns and style
- Assess your audience for each document to improve readability
- Identify basic strategies for crafting effective messages and enhancing comprehension
- Write more concise sentences and paragraphs
- Improve your editing skills
- Apply learnings to improve document quality

course outline

Introductions, Definitions, and Review of Learning Objectives

Role of Writers & Ethical Considerations

Regulations and Good Documentation Practices

Building Submissions and Interconnecting Documents

The Writing Process

- Determining the purpose and use
- Defining your target audience
- Gathering data
- Organizing and structuring your document
- Working with teams
- Planning document timelines

Writing Effective Correspondence

- Choosing the best pattern of delivery
- Writing Emails, agendas, minutes

Mastering the Language

- Making every word count
- Writing effective sentences
- Using the active and paring the passive
- Defining precision, objectivity, and clarity
- Punctuating effectively

- Writing effective paragraphs
- Editing your documents and those of others

Writing Quality Regulatory Reports

- Writing cohesive reports with context
- Writing effective summaries and abstracts
- Representing data accurately
- Editing, proofing, and assuring quality of documents
- Responding to FDA questions or requests for information

Question and Answer Session
Assessment Opportunity

course instructor

Zeinab Schwen is an experienced technical expert, writer, lecturer, and entrepreneur with over 39 years in the pharmaceutical and medical device industries. While working for major pharmaceutical companies, Ms. Schwen gained hands-on experience in drug metabolism, drug development, and clinical trial management. She monitored large multicenter trials and participated in writing and preparing large drug submissions for several Rx therapeutic categories. Ms. Schwen later founded a successful consulting and medical communications company that has been supporting the pharmaceutical, medical device, biologics, and the healthcare industry for over 27 years. In her capacity as the President of Strategic Regulatory Consulting, Ms. Schwen has provided product development, regulatory consulting, submission assistance, and medical communications services to companies nationwide. As a successful lecturer, Ms. Schwen has taught at several Universities and has led numerous regional and international workshops on medical, technical, and regulatory writing. Ms. Schwen has also served on the boards of numerous non-profit organizations focused on women's self-sufficiency, poverty, and other cultural and social justice issues.

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 12 contact hours, or 1.2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)

Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.