COBBLESTONE

COURSE ID 1646

Writing and Enforcing SOPs: Best Practices for Regulated Industries

DIRECTED BY

Louis Angelucci — **Consultant to the Pharmaceutical Industry**

12 Hours

ACCREDITED COURSE

- FDA & ISO Mandates
- Basics of Good Documentation Practices
- How to Structure Accurate & Precise SOPs
- SOP Templates
- Interactive Exercises

about the course

Organizations often face challenges when creating and enforcing effective standard operating procedures (SOPs). Poorly written SOPs are a common cause of deficiencies and observations mentioned in 483s and warning letters issued by the FDA. Therefore, companies operating in regulated industries must understand how to organize and present information for the intended audience and purpose.

To address this issue, this 12-hour accredited training course offers guidance on how to write effective Standard Operating Procedures and Work Instructions to support company activities. Throughout the course, participants will learn how to organize and present information for the intended audience and purpose, as well as how to write clear and readable documents while revising and refining their own and others' writing.

The course provides practical guidance on the purpose and regulatory requirements for SOPs, with a focus on writing from the reader's perspective. Participants will also learn how to structure SOPs to be accurate, concise, and to the point, as well as tips on formatting. Additionally, the course includes discussions on current FDA findings regarding SOP deficiencies and offers practical and effective SOP templates. It also provides guidance for team writing of SOPs and best practices for SOP distribution while discussing good documentation practices.

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 in order to fully participate.

who should attend

This course is intended for all personnel directly involved in the development of standard operating procedures including those responsible for writing validation protocols or execution activities. Beginning or seasoned operational personnel who will participate in team writing and individuals in management who communicate with regulatory agency inspectors will also benefit from attending this course. There are no prerequisites for attending, but a basic knowledge of good manufacturing practices is helpful.

The course will be especially beneficial to:

- Quality Manager, Engineers and Auditors
- Process and Production Supervisors
- Quality Assurance and Control Professionals
- Validation Engineers

learning objectives

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

- Explain the mandates for SOP documentation set forth by the regulators, such as the Food and Drug Administration (FDA), the International Organization for Standardization (ISO), and other governing bodies
- Produce effective written correspondence
- Assess and write to the audience
- Organize and deliver information based on the message
- Structure SOPs using proper English grammar including proper voice and punctuation
- Review and revise SOPs and Work Instructions
- Demonstrate skills in writing and revising documents
- Explain the basics of Good Documentation Practices

course outline

Review of Learning Objectives

Purpose of Standard Operating Procedures

- Mandates for SOP documentation set forth by the regulators, such as the Food and Drug Administration (FDA), the International Organization for Standardization (ISO), and other governing bodies

How to Develop/Write effective written correspondence

- Use of specific words when writing instruction

How to write to the audience

- Know how to organize and deliver information based on the message
- Understand how to structure SOPs

Understand the innate structures of English grammar

- How to create grammatically sound passages

- How the active and passive voices work and how to choose the most appropriate one for the type of writing you are doing

Team writing SOPs

- Advantages
- Creating buy in
- Training the Trainer

SOP writing for Participants

- Participants will be given a topic and asked to write a short SOP, they will have time to discuss how they would approach the writing with a team.

Reviewing and Revising SOPs

Final Questions/Comments/ Discussion

Understanding writing Patterns

- Knowing the answers to questions about the English language

Confidence in writing and revising SOPs

- Practice writing and revising

SOP Distribution

- Routing SOPs for approval
- Role of document control
- Training
- Effective dates

Enforcing SOPs

- Management's role
- Quality Assurance's role
- Personnel's role

Good Documentation Practices

- General requirements
- GDP basics
- Record control
- Modifying records in a compliant manner
- Attachments and printouts
- Examples of documentation errors with attendee participation

Question and Answer Session

Assessment Opportunity

course instructor

Lou Angelucci is a pharmaceutical professional with over 30 years' experience in Quality Assurance, Quality Control, Regulatory Affairs, Validation, consent decree remediation as well as cGMP Compliance in the Medical Device and Pharmaceutical industries

He has worked for several well-known companies including Johnson & Johnson, Bristol-Meyer Squibb, Pfizer, Schering Plough and Merck. His experience has been either as a direct employee or as a contracting consultant while employed at Foster Wheeler and Aker Kvaerner. As a consultant Mr. Angelucci has worked at various project locations domestically and in Europe and Asia. With

these firms he has been involved with auditing, GMP training, Bio-tech consulting as well as FDA audit and PAI readiness training and participation.

Mr. Angelucci is a degreed engineer with two master's degrees in engineering, holds industry certifications with ASQ as a CQE, CQA and CPGP. Previously, he was the ASQ Philadelphia chapter Education Chair. In addition, he holds a PMP certification through the Project Management Institute. He has published numerous articles on the subjects of Validation and compliance and has been a speaker to industry groups such as ISPE, IVT, DIA, PDA, ASQ and CFPA.

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 X contact hours, or X 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.