COBBLESTONE

COURSE ID 2848

# Writing and Enforcing Effective SOPs Basics

DIRECTED BY

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

2.5 HOURS

ACCREDITED COURSE

**Course Topics Include:**

- Purpose of SOPs
- Components of SOPs
- Benefits of SOPs
- Formatting SOPs
- SOP Preparation
- Enforcing SOPs
- Active/Passive Voices
- Review and Revise Effectively
- Utilizing GDP
- Team Writing SOPs
- Regulatory Citation Examples

## about the course

The purpose of this accredited training is to equip participants with the necessary skills for writing effective Standard Operating Procedures (SOPs) that support their company's activities. Throughout the course, participants will learn how to organize and deliver information tailored to the intended audience and purpose, write documents that are clear and easy to read, and revise and refine their own and others' writing. The training covers all the essential components of SOPs and emphasizes formatting documents according to the readers' needs.

Furthermore, this course will examine how participants can tailor their writing style to different audiences and cultures. Also emphasized will be how to effectively foreshadow upcoming events or processes in an SOP to ensure that readers do not overlook crucial information. The overall goal of this training is to equip writers with valuable techniques that keep readers engaged without the use of redundancy or irrelevant details, creating a clear mental picture of the task or job for the reader.

## who should attend

This training will benefit professionals in the pharmaceutical, medical device, biotechnology, cosmetic and food industries as well as those in other FDA regulated industries. It will be especially valuable to professionals in Quality Assurance, Engineering, Validation and Manufacturing. Directors, Managers, Technical writers and General staff charged with the responsibility for creating, reviewing, approving and implementing written standard operating procedures and instructions will find this course highly beneficial as well.

## learning objectives

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

- Apply the mandates for documentation set forth by the regulators, such as FDA, ISO and other governing bodies
- Write effective SOPs and utilizing tools such as flow charts
- Utilize active and passive voices and choose the most appropriate one for the type of writing
- Review and revise documents
- Identify Dos and Don'ts of SOP writing
- Participate in team writing SOPs
- Examine work instructions, forms and attachments

## course outline

**Review of Learning Objectives**

**Module 1: The purpose and benefits of Standard Operating Procedures**

- Components of SOPs
- SOP necessity
- SOP responsibilities
- Types of SOPs
- Document mapping
- Benefits of SOPs
- Quiz and Review

**Module 2: Developing and Writing Effective Written Correspondence**

- Use of specific words when writing instruction
- Organizing and delivering information based on the culture of the audience
- Structuring the components of SOPs to be clear, concise, and to the point
- Structuring and formatting SOPs
- How the active and passive voices work and
- Defining a good SOP
- Quiz and Review

**Module 3: Team writing SOPs**

- Individual taking part in SOP Writing
- SOP training
- SOP Management and Review
- Auding for SOPs
- SOPs and GDP

- SOP enforcement
- Quiz and Review

**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 2.5 contact hours, or .3 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.