
Writing Standard Operating Procedures

Purpose

Attendees learn to develop more meaningful, useful, and audit worthy procedures.

Objectives

At the completion of the class, students will be able to:

1. State the role of procedures.
2. Conduct a task analysis and knowledge assessment.
3. Determine appropriate procedure content.
4. Evaluate consistency and functionality of procedure format.
5. Write SOP statements and instructions.
6. Identify the procedures intended target audience.
7. State the regulatory guidelines for writing procedures.
8. Describe the procedure change control process.
9. Use procedures for training.

Prerequisite

Attendees should have a solid understanding of CGMPs and have followed or work with procedures in a regulated industry.

Who should attend this class?

Anyone who is responsible for writing, editing, reviewing or approving procedures should attend this class.

About the class

1. Students use existing procedure to edit or new procedures that need to be written to practice the use of tools taught in this class.
2. The optional final exam is approximately 25 questions.
3. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
4. This class can accommodate up to 12 people.
5. Duration: 8 hours.

Topics Covered

Introduction

1. CGMP Requirements
2. The role of procedures
3. How the FDA and our company use procedures
4. CGMP procedure related observations

Task Analysis

1. Using flow charts
2. Incorporating skills and knowledge in procedures
3. Decision making as a process in procedures
4. Tools and aids to job performance
5. Sources of procedure information
6. Step and task sequencing in procedures
7. **Activity:** *Writing clinic*

Procedure Format

1. Sections of procedures
2. Company-specific formats and sections
3. Using each section
4. **Activity:** *Writing clinic*

Human Factors

1. Cognitive capacity
2. Structuring the procedure
3. Assuring greater retention
4. Identifying the target audience
5. Literacy and the procedures
6. Tricks to make procedures more readable
7. FDA perspective on procedure readability and comprehension
8. **Activity:** *Writing clinic*

Writing the Procedure

1. Action words for simplicity
2. Specific versus general statements
3. Ranges versus discrete values
4. Attachments
5. Other supporting documents
6. **Activity:** *Writing clinic*

Approval and Change Control

1. Review and approval responsibility
2. Review frequency
3. Tracking procedures through the change process

Procedures and Training

1. Using the procedure for training
2. How to conduct training
3. From the procedure to performance coaching

This class is best taught in a computer lab. If your company does not have a computer lab, we can ship one to your site for this class usually for less than \$500 total extra charge.

This class is always customized to reflect the language and procedure structure of the site. Class us to discuss the details in more detail.