Writing Compliant, Practical SOP's

This course guides the participant through the process of writing Standard Operating Procedures that meet cGMP requirements <u>and</u> serve their business purpose. Participants will learn the three critical requirements for a successful SOP. They will learn how to write SOP's that are compliant, yet flexible and dynamic; allowing you to keep up with the pace of business in the 21st century.

Who Should Attend: All personnel who write or revise or use SOP's, and their managers.

Class Length: One day

Maximum Class Size: 20

Course Prerequisites: Participants must have a working knowledge of cGMP's.

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- The regulatory requirements and draft guidelines

- Documents that must be controlled

- The purpose of documentation

- Definition of Standard Operating Procedures (SOP's)

- How documents should be controlled

- The purpose of signatures and initials of individuals

- The key parts of an SOP

- How to write an SOP that will get used

- The importance of writing in the active voice

- Proper use of past, present, and future tenses

- Why concise, Spartan language is better

- How much detail is required

- Why you should know your audience

- Proofreading, reviewing, and revising documents

- Training requirements

- SOP Practical Lesson

    o   Design your own SOP

    o   Perfect your writing skills