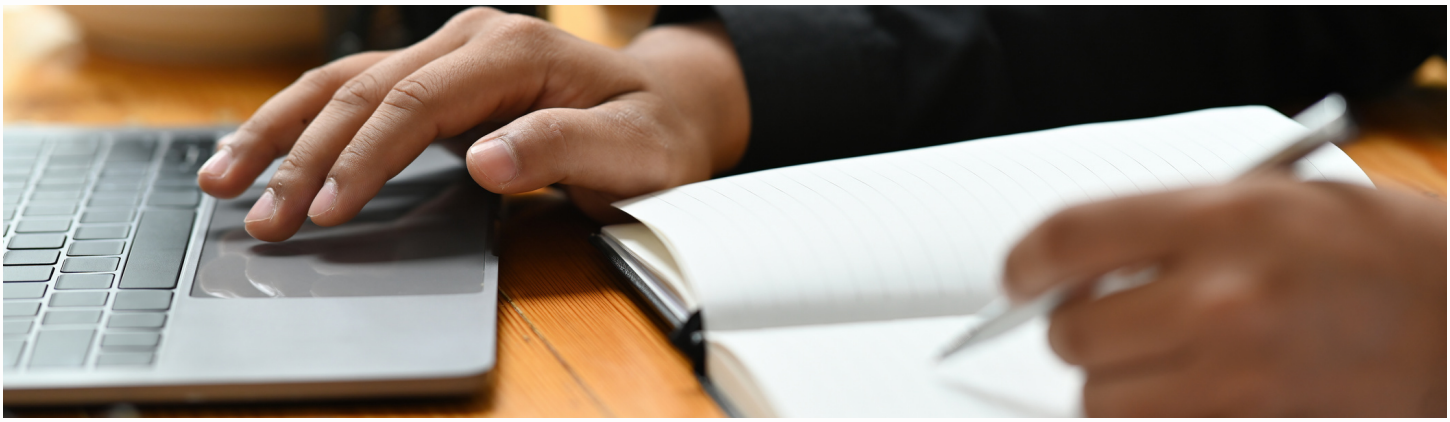
Writing and Implementing SOP in Laboratory for FDA, EPA, and OSHA Compliance

2 Days Seminar (8 Hours total), Instructor led course

8.0 RAC CREDITS



INTRODUCTION

SOP in laboratory is one of the top-most priorities for professionals. Starting from freshly hired interns to seasoned researchers – a standard operating procedure maintains the uniformity of the lab for every worker.

This is specifically important to handle critical chemicals during drug manufacturing process. For instance, hazardous chemicals like carcinogens, acutely toxic chemicals, and reproductive toxins need to be handled with care.

COURSE OVERVIEW

As the name suggests, an SOP in laboratory is a detailed document that consists of meticulous steps to be followed by the professional. The core purpose of this document is to streamline the workflow in laboratory. However, it is not sufficient to know SOP in laboratory by heart.

An SOP training plays an essential role in certifying that every professional can develop a standardized protocol for the laboratory. This will not only prevent errors and risks, but make it easier for everyone to implement a task accurately.

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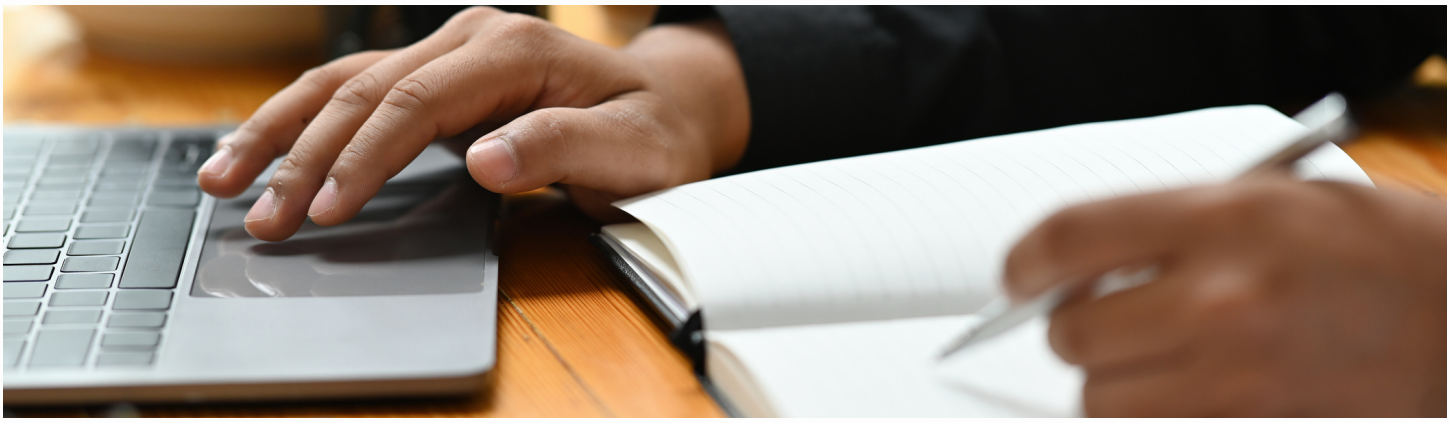

TRAINING AGENDA DAY 01

Session 1
- What is the intention and role of SOPs?
- What tasks require SOPs?
- How the network of SOPs within the Lab support each other?
- How is an SOP structured/ formatted?

Session 2
- What are the compliance requirements for an SOP?
- Descriptions of the roles and responsibilities of people in the SOP process.

Session 3
- Description of the various standard methods.
- The Regulatory Compliance Method.
- The Scientific Published-Literature Method.
- The Industrial Standard Method (ASTM and ISO methods).
- How to assess if a standard method can be used as is as the SOP?
- Conversion to an acceptable SOP from a standard method.

Session 4
- How to create an SOP?
- The SOP for a new task.
- The SOP for a new methodology.
- The SOP for a Standard method.

TRAINING AGENDA DAY 02

Session 1
- The Interplay within the lab to improve the draft SOP.
- Reviewing the first attempt.
- Iterations and how to assess the reaching of compliance.

Session 2
- The Implementation of the SOP.
- Training, The Documentation of Initial Training and the On-Going Proficiency testing as a Requirement.

Session 3
- Monitoring and Assessing the SOP for Needs of Changes.
- Modification, Updating, and Revising an SOP. When should an SOP be revised?
- Revising the SOP and Its Documentation and Approval.
- The Use of a Method Timeline to Track Changes.

Session 4
- The Requirements in Archiving and Documentation.
- Which SOP is to be used when?
- Other requirements that must be included: Facility requirements, purchasing guidelines, safety issues methods of reporting (and standard forms and information to be reported).

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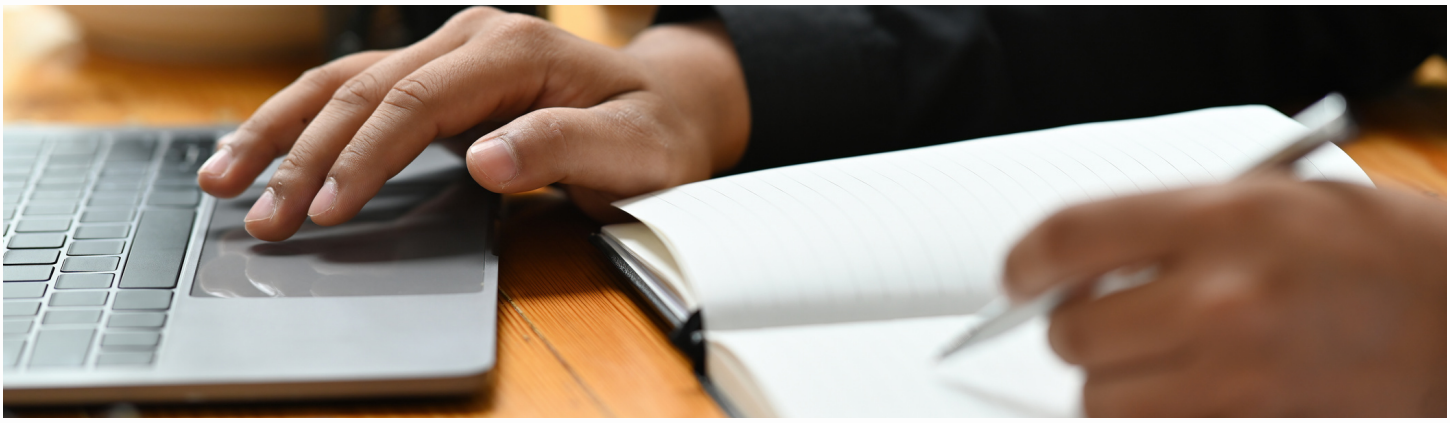

WHO WILL BENEFIT

- Managers & Supervisors: Assess the quality of work and guide beginners to keep the protocol uniform in all the steps.
- Quality Analysts & Internal Auditors: Makes it easier to figure out loopholes and bridge the gaps before the final FDA or EPA inspections.
- Scientists & Research Associates: As a principal investigator, you will be able to direct the entire course of experiment for the team.

KNOW YOUR FACULTY

Mr. John C. Fetzer holds 30 years of experience in handling large-scale laboratory experiments. Starting from methods development to coming up with novel protocols – he understands the core of laboratory procedures. Moreover, working on GLP protocols for FDA compliance and building an efficient team is an added experience he offers during the SOP training.

WCS World Compliance Seminars

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