COBBLESTONE

COURSE ID 2864

REVISED!

# Standard Operating Procedure (SOP) and Standard Test Method (STM) Requirements

Designing, Development, Drafting, Processing and Approval of An Effective and Compliant SOP or STM


DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

**Course Topics Include:**

- Regulatory Requirements
- Effective Structure of SOP and STM
- Related Documents and Policies
- Preventing Internal and External Conflicts

## about the course

Designing an effective Standard Operating Procedure (SOP) and Standard Test Method (STM) is the pre-requisite to complying with the different regulations guiding the manufacturing and testing of products. A well-established procedure and test method improves the numbers of manufacturing, testing and personnel deviations which indirectly affects the quality and life cycle process of a manufactured product.

This 90-minute accredited training course will provide the attendee the ability to understand the sequence of designing, development, drafting, processing and approval of an effective and compliant SOP or STM. The industry applications, regulations, content, organization, development, management process/cycle, content and formatting of an SOP and STM will be discussed. Understanding these requirements will aid in the reduction of manufacturing and testing errors arising from an unclear, poorly planned/executed and vague procedures that are left to several varying interpretations and applications which may sometimes lead to non-compliance.

## who should attend

This webinar will provide a great resource to Pharmaceutical, Biotechnology, Biologics, Drugs, Medical Device, In-vitro Diagnostics Industry personnel within the following functions: Quality Control, Quality Assurance, Microbiologist, Chemist, Analysts, Manufacturing, Validation, Facilities, Materials, Engineering, Vendors/Suppliers, all Technical Writers and SOP/STM Users, Regulatory Affairs, and all levels of management.

## learning objectives

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

- Describe the application and regulatory requirements of a well-designed Standard Operating Procedure (SOP) or Standard Test Method (STM)
- Develop, design, plan, draft, process, approve and maintain an effective and compliant SOP or STM
- Prevent internal and external procedural conflicts when drafting a new SOP or STM
- Reduce the number of personnel, procedural and test method deviations emanating from a poorly drafted SOP or STM
- Appreciate the role and impact of a well-designed SOP or STM during the manufacture and testing of a cGMP product
- List the benefits of adequate planning, development, and life cycle process of an SOP/STM in achieving compliance while improving efficiency

## course outline

**Review of Learning Objectives**
**Module 1**

- Types of Operating Procedures or Test Methods
- Industry Applications and Regulations Guiding Standard Operating Procedure (SOP) and Standard Test Methods (STM)
- Importance of Standard Operating Procedures (SOP) and a Standard Test Methods (STM)
- Considerations when Designing or Planning to Draft an SOP or STM

**Module 2**

- How to Effectively Structure an SOP or STM
- How to Interface an SOP or STM with Other Related Documents or Policies
- How the Detailed Content of an Effective SOP or STM Should Look

**Module 3**

- Signs of an Ineffective SOP or STM
- SOP or STM Planning Process and Life Cycle
- SOP or STM Management and Life Cycle
- Formatting the SOP/STM
- Reviewing and Approving the SOP or STM

**Question and Answer Session**

**Assessment Opportunity**

## course instructor

**Charity Ogunsanya** has more than 30 years of extensive experience within the Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology and Medical Device Industries and has been the Microbiology, Sterility Assurance, Contamination Control, Aseptic processing, Quality Control Subject Matter Expert (SME) for multiple fortune 100 companies.

She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and has a Master's degree from the Advanced Academic Master's Biotechnology Program at the Johns Hopkins University with concentration in Biotechnology/Biodefense. She is the CEO/ Owner of her consulting firm named Pharmabiodevice Consulting LLC. Her consultancy provides support to Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology and Medical Device Industries.

## Accreditations

**International Accreditors for Continuing Education and Training (IACET)**
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