

COURSE OBJECTIVES:

- Clarification of types of SOPs required by GLP regulations
- Procedures to be established as written SOPs to create a quality GLP system
- Simplifying SOP organization and format - the importance of a good design
- Effective user-friendly SOPs
- Writing for the intended reader
- How to avoid SOP pitfalls
- "Poorly written" SOPs
- Establishing a workable system for documentation of SOP deviations
- Document control, distribution and maintenance of SOPs

GLP REGULATIONS REQUIRE

that test facilities have written SOPs which are adequate to insure the quality & integrity of GLP studies and supportive functions.

THIS WORKSHOP IS DESIGNED FOR

Scientists, Management, QA Professionals, Document Control Coordinators, & Support Personnel involved in development and implementation of GLP quality systems, and/or in the writing or review of SOPs.

SOP WRITING & REVIEWING EXERCISES

are incorporated throughout the workshop to reinforce the newly acquired knowledge, tools & techniques via immediate direct, practical application.

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GLP Standard Operating Procedures Workshop

presented by
**ROSETECH
CONSULTING**

GLP Standard Operating Procedures Workshop

☑ OVERVIEW

- WHAT ARE SOPs
- WHY ARE SOPs NECESSARY
- GLP REGULATIONS
- FDA/EPA/OECD

☑ GLP REQUIRED SOPs

- QUALITY SYSTEMS
- ROLES & RESPONSIBILITIES
- PERSONNEL & TRAINING
- QUALITY ASSURANCE
- FACILITIES & EQUIPMENT
- COMPUTERIZED SYSTEMS
- DATA HANDLING, STORAGE, RETRIEVAL
- PROTOCOLS & REPORTS
- TEST MATERIALS
- LAB OPERATIONS
- TEST SYSTEMS
- SPECIALIZED PROCEDURES

☑ SOP DESIGN

- ORGANIZATION
- FORMAT
- CONTENT

☑ EFFECTIVE SOPs

- WRITING CLEAR INSTRUCTIONS
- USER-FRIENDLY PROCEDURES
- WRITING FOR THE READER
- EFFECTIVE WRITING
- VOICE
- TENSE
- APPROVAL

☑ AVOIDING SOP PITFALLS

- PITFALLS THAT LEAD TO DEVIATIONS
- COMPLICATED/MULTISTEP PROCEDURES
- WAYS TO AVOID PITFALLS
- POORLY-WRITTEN SOPs
- "REAL LIFE" EXAMPLES

☑ SOP DEVIATIONS

- DEVIATIONS VS. AMENDMENTS
- WHEN/HOW TO DOCUMENT
- AVOIDING DEVIATIONS
- TOOL FOR RECONSTRUCTIBILITY
- IMPORTANCE OF DOCUMENTATION

☑ SOP AS TOOLS

- STANDARDIZATION/CONSISTENCY
- STUDY PROCEDURES
- TRAINING
- AUDITING
- RECONSTRUCTIBILITY

☑ DOCUMENT CONTROL

- RESPONSIBILITIES
- CONTROLLED DOCUMENTS
- INVENTORY
- DISTRIBUTION
- HISTORICAL SOPs
- ARCHIVAL

☑ SUCCESS FACTORS

- ORGANIZATION
- USABILITY
- UNDERSTANDING
- ACCESSIBILITY
- CONTROL

☑ COMPLIANCE

- SOPs & OTHER DOCUMENTS
- ADHERENCE TO SOPs
- COVERING THE GLPs
- 483s & WARNING LETTERS