Course Objectives:

- Improve understanding of GLP regulations that apply to roles and responsibilities
- Learn how to effectively & compliantly execute quality GLP studies
- Improve writing skills & generate compliant study protocols & reports
- Improve documentation & reconstructibility of study file
- Apply newly learned skills & knowledge to problem prevention, mitigation, & resolution
- Increase productivity & reduce non-productive time, cost, and resources

This intense multi-day workshop covering all aspects of GLP study conduct goes beyond typical classroom training.

Interactive, Real-Life exercises are incorporated into the workshop to reinforce the newly acquired knowledge, tools & techniques through immediate direct, practical application.

valuable knowledge, skills, tools and techniques can then be immediately utilized in the workplace to perform quality GLP studies with increased productivity, compliance and study reconstructibility.

Celeste Rose, RQAP-GLP, RoseTECH Consulting, Inc. is a Registered Quality Assurance Professional with over 20 yrs experience in GLP & 10 yrs as a Study Director.

Contact us for more details

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GLP Study Director Boot Camp

presented by

RoseTECH Consulting

Study Director Boot Camp

☑ Overview

- Good Laboratory Practices
- Roles & Responsibiilities

☑ Personnel

- Study Personnel
- Animal Technicians
- Maintenance & Support
- QA
- Management
- Test Sites
- Principal Investigators
- Sponsors

☑ Phases/MultiSite

- Method Validation
- Dose Analysis
- Bioanalytical
- PK/TK
- Histopathology
- Clinical Pathology

☑ Study Conduct

- Study Design
- Protool Elements
- Unusual Events
- Data Generation

☑ Study Files

- Study File Organization
- Study File Review/Approval
- Archival of Study File

☑ Test System

- Facilities & Supplies
- Care & Husbandry
- Specimens
- Technician Training
- IACUC
- Records

☑ Test Materials

- Test & Control Materials
- Characterization & Stability
- Dose Analysis
- Referenece Standards

☑ Lab Operations

- Equipment
- Logbooks
- Reagents & Solutions

☑ Effective Writing

- SOPs
- Protocols and Reports
- Deviations & Amendments
- Contributing Reports

☑ Documentation

- Recordkeeping Practices
- Notebooks & Record Formats
- Study Reconstructibility

☑ Success Factors

- Study Startup Meetings
- Study Followup Meetings
- Project Management
- Tools
- Soft Skills
- Effective Communication

☑ Audits&Inspections

- In-Study Inspections
- Preparation for QA Review
- Protocol & Report Audit
- Responding to QA Findiings

☑ Compliance

- Regulatory Guidances
- Compliance Statements
- 483s & Warning Letters