SOPs for FDA-Regulated Industry: Best Practices to Withstand FDA Expectations: 2-day In-person Seminar

Description:

One of the best ways to ensure that an organization meets its regulatory obligations is to follow SOPs. SOPs are standardized procedures and processes prepared with enough detail to ensure that tasks are performed consistently each time they are done. SOPs are also required to be in compliance with regulations and guidelines internationally, across all regulated functions. Lack of SOPs and not following SOPs are often cited in regulatory inspections as deficiencies that must be corrected. Poorly prepared SOPs or poor compliance with existing SOPs can compromise a drug development program, an effective quality system, and may result in product recalls.

This workshop will explore what SOPs are, what they are used for, when they are required, how to write them effectively for compliance and for implementation within the organization, and how to ensure effective communication and training of procedures within the SOPs.

Learning Objective:

- Regulatory requirements for SOPs
- Legal requirements for SOP creation and maintenance
- Types of SOPs
- Formats and essential components of SOPs
- How to effectively write an SOP to ensure compliance
- SOP training and implementation
- Deviations from and changes to SOPs

Contents:

Day One(8:30 AM - 4:00 PM)

Registration Process - 8:30 AM - 9:00 AM

Session Start Time - 9:00 AM

9:00 - 10:00 AM: SOPs for a given organization: FDA Requirements
- US and EU Regulations describing SOPs
- Regulatory requirements for different organizations: sites, manufactures, labs
- Requirements for various products: Drugs, biologics, devices, diagnostics, clinical labs
- What processes do not need written SOPs
- SOPs verses working practices and draft scripts
- Legal requirements for creating and maintaining SOPs

10:00 - 10:15 AM: Break

10:15 - 12:00 Noon: Where to Start: Developing a Strategy
- Listing tasks for a given organization
- Qualifications of writing leaders and teams
- Resource allocation and time-lines
- Policies and procedures
- Using Templates: Self-created and acquired

12:00 - 12:45 PM: Lunch

12:45 - 2:15 PM: How to Get Started
- List of SOPs for different organizations: Clinical sites, manufacturing facilities, labs, etc
- Process development and developing SOP on SOPs
- Prioritizing tasks
- Minimum requirements for SOPs
- Risk-based approach for SOPs
- Types of SOPs

2:15 - 2:30 PM: Break

2:30 - 3:30 PM: Writing an SOP: 5 Steps to a Good SOP
- Format for an SOP
- Essential Components of an SOP
- Task split, distribution, and attribution
- Documentation: Checklist, forms, and reports
- Annotations

Day Two (8:30 AM - 3:30 PM)

8:30 - 10:00 AM: Essentials of a SOP Driven Process
- What is Process Mapping and how can it be best used?
- Categorization and organization of SOPs
- Rules for electronic SOPs in the cGMP, GLP and GCP environment
- Maintaining SOPs
- Best practices for access control and distribution
- Archiving, retiring, and audit trails for SOPs

10:00 - 10:15 AM: Break

10:15 - 12:00 Noon: Effective Writing Strategies
- Writing Exercise for SOP
- Style, tone, and content arrangement
- Best practices for SOP approval process
- Electronic verses paper SOPs

12:00 - 12:45 PM: Lunch

12:45 - 2:15 PM: Education and Training on an SOP
- Best practices for training and documenting
- Periodic reviews
- Tools for SOP tracking and training validation
- Train the trainer programs
- Adapting Generic, Institution, or Sponsor SOPs for your Needs
- SOP updates
- Dealing with deviations

2:15 - 2:30 PM: Break

2:30 - 3:30 PM: Getting Ready for FDA Audits of SOPs
- Common FDA 483s and Warning Letters regarding SOPs
- Logistics of an FDA audit
- Best practices for coordinating FDA review of SOPs
- Addressing FDA findings
- Responding to an FDA 483
- Dos and Don'ts of an FDA audit

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