BOSTON EVENTS LIST

SOP Development and Implementation for the FDA-Regulated Industry

Date : Jun 14, 2018 - 09:00 AM

Event URL : http://www.BostonEventsList.com/events/sop-development-and-implementation-for-the-fda-regulated-industry-jun-2018

Organizer : GlobalCompliancePanel

Venue :

Location : Four Points by Sheraton Boston Logan Airport Revere, MA,
Boston, MA, US, ZIP: 10001

SOP Development and Implementation for the FDA-Regulated Industry

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.

Why should you attend:

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.

Areas Covered in the Session:

- Regulatory requirements for GCP SOPs
- Regulatory requirements for GMP 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

Who Will Benefit:

- Directors
- Managers
- Supervisors
- Auditors
- Regulatory operations
- Clinical investigators, site management and contracting personnel
- Clinical operations
- Project managers
- Data management
- Medical writers
- Compliance officers

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Event Categories :