2019 Update: How To Write Effective SOPs For FDA Inspection & Regulatory Compliance

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PURPLE VERTEX

This webinar will instruct the participant on how to write, organize, and maintain SOPs and train personnel in a way that will ensure compliance in a way that is concise, reproducible and easy to follow. It will begin with a strategic view of SOPs in a company and how SOPs can help streamline operations in addition to ensuring regulatory compliance. This will be followed by an explanation on how to get from regulations to the SOP. Finally, Best Practices for creating, implementing and maintaining SOPs using a risk-based approach and getting SOPs ready for inspection will be presented.

Virtually every FDA inspection includes a review of SOPs and adverse agency findings are often the result of SOP administration issues.

LEARNING OBJECTIVES

- SOPs and their relation to the regulations
- SOPs as part of the company's regulatory infrastructure
- SOP on SOPs and how to ensure conciseness, consistency, and ease of use
- Risk-Based approach on SOP Best Practices for creation and maintenance
- Training on SOPs
- Tools for SOP tracking and when is validation required
- What the FDA looks for in SOPs during an inspection

WHY SHOULD YOU ATTEND

Standard Operating Procedures (SOPs) are required by law for companies that are regulated by the Code of Federal Regulations such as Title 21 and Title 493. Yet there is no guidance on how to write, organize and maintain SOPs. Consequently, SOPs are frequently written in a way that makes compliance difficult or downright impossible. Worse, this often leads to many regulatory errors that first come to light during a FDA audit.

This webinar will show you how to write, organize, and maintain SOPs and train personnel in a way that will ensure compliance in a way that is concise, reproducible and easy to follow.

INSTRUCTOR PROFILE

ANGELA BAZIGOS

Angela Bazigos is the CEO of Touchstone Technologies Inc. She has 40 years of experience in the Life Sciences & Healthcare Industries. The experience combines Quality Assurance, Regulatory Compliance, Information Technology, Project Management, Clinical Lab Science, Microbiology, Food Safety, and Turnarounds. Past employers/clients include Roche, Novartis, Genentech & PriceWaterhouseCoopers, Public Health Service. Positions include:

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