

SOPs and Policies for the 21st Century

Why Less Is More

Multi-attendee discounts are available!

NOV. 1-2, 2018
EMBASSY SUITES SAN FRANCISCO
AIRPORT-WATERFRONT
SAN FRANCISCO, CA

AN INTERACTIVE WORKSHOP PRESENTED BY CERULEAN LLC AND FDANEWS

AGENDA

DAY 1

8:30 a.m. – 9:00 a.m. Registration and Continental Breakfast

9:00 a.m. – 9:15 a.m. Introduction and Welcome

9:15 a.m. – 10:45 a.m. SOPs and Policies - What's Really Required?

- Core regulatory requirements — FDA, EMA, ISO and more
- Guidances — what you don't know will hurt you
- How to quickly parse warning letters for SOP expectations
- FDA investigator questions to expect about your SOPs and policies
- *Interactive Exercise* — Attendees act as FDA investigators and company personnel to review SOPs to identify the proof FDA expects to see during an inspection to prove the SOP was followed

10:45 a.m. – 11:00 a.m. Break

11:00 a.m. – 12:00 p.m. Practical Reality — the Business Costs of Poor SOPs and Policies

- Real world business costs of poor SOPs and policies
- Practical quality costs of poor SOPs and policies
- *Interactive Exercise* — Attendees role-play through several case-study SOPs and compare typical SOPs to their modernized, simplified and streamlined versions

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:15 p.m. Critical SOP Components to Prove Compliance

- Take advantage of the Policy-SOP-Task Outline hierarchy
- Understand the role of adult comprehension and retention
- SOP format and structure for the 21st century — why less is more
- Why every SOP needs to generate a record
- How to use forms, checklists, and templates to reinforce compliance
- Where do definitions belong in the era of wikis and intranets?

2:15 p.m. – 2:30 p.m. Break

- 2:30 p.m. – 4:30 p.m.** Process Mapping
- Why FDA, your staff and your management like to see process maps
 - Why process maps help in the “big picture”
 - Process mapping rules
 - How to process map like a pro
 - Ways in which to use a process map — from training to auditing
 - Sneaky ways to use process maps to achieve 100% compliance
 - *Interactive Exercise* — Attendees work in teams to process map several case study SOPs

- 4:30 p.m. – 5:00 p.m.** Day One Wrap Up and Review
- *Interactive Exercise* — Attendees identify 3 compelling reasons for personnel at their own company why they should update and streamline their SOPs and policies

DAY 2

- 9:00 a.m. – 9:15 a.m.** Day Two Welcome and Quick Learning Recap

- 9:15 a.m. – 10:30 a.m.** SOP Metrics to Prove Effectiveness
- Why metrics are important to a culture of compliance
 - Why management (and FDA) want to see metrics
 - Simple metrics that work for SOPs and policies
 - When to review metrics — and when not to
 - *Interactive Exercise* — Attendees draft a follow-up action plan from several case study SOP metrics to improve compliance

- 10:30 a.m. – 10:45 a.m.** Break

- 10:45 a.m. – 12:00 p.m.** Advanced Tactics to Reduce Overhead and Lighten Your Workload
- How to best use photographs in SOPs
 - Mistakes to avoid in your “SOP of SOPs”
 - Steps to foster self-compliance using self-assessments
 - How to write an SOP to oversee an activity you’ve outsourced
 - The easy — and critical — role for senior management
 - *Interactive Exercise* — Draft a communication to be sent out by your senior team to all company employees about Quality Systems SOPs that will actually lower your workload and encourage self-compliance

- 12:00 p.m. – 1:00 p.m.** Lunch

- 1:00 p.m. – 2:00 p.m.** Writing for the Right Audience
- Tips on writing for a line worker
 - Tips on writing for an office worker
 - Tips on writing for scientists and engineers

- Tips on writing for management
- *Interactive Exercise* — Attendees analyze and select phrases, words, and document structures best suited to ensuring compliance among different types of workers, managers, and contractors

2:00 p.m. – 2:15 p.m. Break

2:15 p.m. – 3:30 p.m. Making SOP Training “Sticky”

- How to design a training session for adult information retention
- How to craft engaging slides and other training materials
- Types of SOP hands-on materials for the factory line and the office
- Ways to use training to handle one-off details not in SOPs
- *Interactive Exercise* — Work in teams to outline a sample, hands-on training session for two different SOPs

3:30 p.m. – 4:00 p.m. Building Your Business Case to Streamline Your SOPs & Policies

- *Interactive Exercise* — Attendees work with the expert instructor to draft their own personal, business case and prioritized plan for streamlining and modernizing their quality system SOPs and policies

4:00 p.m. – 4:30 p.m. Wrap Up and Final Questions

4:30 p.m. Adjournment