FDANEWS PRESENTS THE

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SOPs for the 21st Century
Why Less Is More

DEC. 15-16, 2016
AMA EXECUTIVE CONFERENCE CENTER
ARLINGTON, VA (WASHINGTON, DC)

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.	**Adjourn Workshop**