VIRTUAL WORKSHOP

Modern SOP and Quality Systems: Streamlined, Effective and Flexible Compliance for the 21st Century

Tuesday, May 11 & Thursday, May 13, 2021, 10:00 am – 4:30 pm EDT
Presented by WCG FDAnews and Cerulean Associates LLC

Day 1
Tuesday, May 11, 2021

10:00 AM **Modern SOP and Quality Systems Live Session-Day 1**
10:00 AM – 4:30 PM EDT

- SOPs and Policies – What's Really Required?
- Remote Inspection Reviews of SOPs and Policies
- Critical SOP Components to Prove Compliance

10:05 AM **Welcome, Verification of Attendee Webinar Tools, Session Overview**
10:06 AM - 10:15 AM EDT

- Review of connectivity and interactive tools
- Session agenda overview
- What to do in case of connectivity issues

10:15 AM **SOPs and Policies - What's Really Required?**
10:15 AM - 11:30 AM EDT

- Core regulatory requirements – FDA, EMA, ISO and more
- FDA investigator questions to expect about your SOPs and policies
- Calculating the real-world-costs – monetary and quality – of poor SOPs

11:30 AM   **Morning Break**
11:30 AM - 12:00 PM EDT

12:00 PM   **Remote Inspection Reviews of SOPs and Policies**
12:00 PM - 1:00 PM EDT

- Why forty years' worth of onsite inspections has led to bad habits that emerge during remote/virtual inspections
- Most common issues that surface when an SOP is reviewed remotely
- Example SOP extracts and follow-up questions they generated from recent remote inspections
- Open Q&A at end of mini-session

1:00 PM   **Lunch Break**
1:00 PM - 2:00 PM EDT

2:00 PM   **Critical SOP Components to Prove Compliance**
2:00 PM - 3:30 PM EDT

- Take advantage of the Policy-SOP-Task-Outline hierarchy
- Use "completion checklists" in lieu of work instructions
- Understand the role of adult comprehension and rentention
- 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
- Rapid overview of use of photos and process maps
- Where do definitions belong in the era of wikis and intranets?
- Open Q&A at end of mini-session

3:30 PM   **Afternoon Break**
3:30 PM - 4:00 PM EDT

4:00 PM   **Wrap Up and Review**
4:00 PM - 4:30 PM EDT

Day 2
Thursday, May 13, 2021

10:00 AM **Modern SOP and Quality Systems Live Session-Day 2**
10:00 AM – 4:30 PM EDT

- Writing for the Right Audience
- Quick SOP Metrics for Management and Quality
- Making SOP Training "Sticky"

10:05 AM **Welcome, Verification of Attendee Webinar Tools, Session Overview**
10:05 AM – 10:15 AM EDT

- Review of connectivity and interactive tools
- Session agenda overview
- What to do in case of connectivity issues

10:15 AM **Writing for the Right Audience**
10:15 AM – 11:30 AM EDT

- 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
- Quick refresher on using photographs and process maps
- Fostering self-compliance through forms, checklists and departmental self-assessments
- Interactive Exercise – Instructor displays and attendees analyze and select phrases, words, and document structures best suited to ensuring compliance among different types of workers, managers, and contractors
- Open Q&A at end of mini-session

11:30 AM **Morning Break**
11:30 AM – 12:00 PM EDT

12:00 PM   **Quick SOP Metrics for Management and Quality**
12:30 PM – 1:00 PM EDT

- Metrics that work for a culture of compliance (e.g., for FDA, et al)
- Metrics that work for management (e.g., for business optimization)
- How to calculate the above metrics
- *Interactive Exercise* – Instructor displays different types of metric samples and attendees determine – based on their company management – which would resonate for their goals

1:00 PM   **Lunch Break**
1:00 PM – 2:00 PM EDT

2:00 PM   **Making SOP Training "Sticky"**
2:00 PM – 3:00 PM EDT

- 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 – Instructor displays example SOP topics and attendees identify best – and second best – training approaches

3:00 PM   **Afternoon Break**
3:00 PM – 3:30 PM EDT

4:00 PM   **Wrap Up and Review**
3:40 PM – 4:00 PM EDT