

July 17-18, 2014 • Embassy Suites Raleigh • Durham Airport/
Brier Creek, Raleigh, NC

Creating Effective SOPs

*How to Turn a Trouble Spot Into
a Collaborative Success*

The FDA has made it very clear that your SOPs may not pass inspection. You need to prove that you have properly written documents that capture your specific processes — and that you have educated your workforce to understand and follow them.

Register for this must-attend workshop, and you will learn:

- 10 writing tips that help you create clear, concise SOPs ... every time
- 3 essential elements of all great SOPs
- 6 things you **MUST** consider when critiquing your own SOPs
- Best practices to rely on for SOP approval, review and revision
- 8 ways to tell if employees are following your SOPs
- Review samples of well written and poorly written SOPs



DAVID DILLS, Dills Consulting

"David is well skilled in SOPs, content, format and development. He has a unique way of incorporating his knowledge and best practices with regard to FDA current practices into this seminar. Kudos to you David."

Alan Johnson, Tech Writer II, Forest Laboratories

Creating Eff

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WORKSHOP AGENDA

DAY ONE

8:00 A.M. – 9:00 A.M. REGISTRATION/ CONTINENTAL BREAKFAST

9:00 a.m. – 10:30 a.m. FDA and International/ Regulatory Requirements and Expectations

- Rapid review of FDA and international requirements
- How the FDA trains its investigators to review procedures/SOPs and what company auditors should be reviewing
- Review of recent FDA warning letter citations/Form 483 observations specific to operational procedures
- INTERACTIVE EXERCISE! Getting your feet wet — small group review of sample SOPs to assure everyone is on the same page

10:30 A.M. – 10:45 A.M. BREAK

10:45 a.m. – 12:00 p.m. Best Practices for SOP Development and Formatting

- 10 writing tips you need to create clear and effective SOPs
- What works and what doesn't in formatting and content
- INTERACTIVE EXERCISE! Analyze and critique templates/SOP examples
- What writing style are you? Analyzing various styles and determining what best suits your purpose

12:00 P.M. – 1:00 P.M. LUNCH

1:00 p.m. – 2:00 p.m. Step-by-Step Guide to Determining Optional SOP Formats

- Flow diagram and developing the process
- How many steps and sub-steps are there in a procedure?
- What is the objective of an SOP (Purpose)
- What is the applicability and use of a SOP (Scope)

- Who will perform tasks (Responsibility)
- Who will ensure implementation of procedure (Accountability)
- How tasks will be performed (Procedure)

2:00 p.m. – 3:00 p.m. What's in a Word? Choosing Content and Structure That Creates Effective SOPs

- Examples of content and structure from GMP, GLP, GCP environments
- INTERACTIVE EXERCISE! Bring in your toughest, most problematic SOPs and we'll review, critique and offer suggestions

You know you have them. Those problematic SOPs that always cause headaches for you and your colleagues. What you need is a fresh set of eyes. Bring in your SOPs and allow the expert staff — and your fellow attendees — to tweak them to perfection. This hour alone is worth the price of admission.

3:00 P.M. – 3:15 P.M. BREAK

3:15 p.m. – 5:00 p.m. Maintenance of SOPs — It Doesn't Have to Be Such a Burden

- Creating efficient review and approval procedures that fit your corporate structure
- Best practices for SOP review, approval, and revision
- Breaking down silos — how to develop a corporate/department-wide SOP implementation process
- Tips for document distribution, retrieval and archiving
- Determining who should be the "gatekeeper" and who should maintain your SOP library

DAY TWO

8:00 A.M. – 9:00 A.M. CONTINENTAL BREAKFAST

9:00 a.m. – 10:30 a.m. Reminders From Day One and Advanced SOP Writing Techniques

- Can an SOP be perfect? Reviewing well written SOPs
- 3 things all great SOPs contain
- Balancing the concerns of underwriting and overwriting — 6 things to consider when you critique your own SOPs

10:30 A.M. – 10:45 A.M. BREAK

10:45 a.m. – 12:00 p.m. Compliance and Training: Even the Best Written SOPs Will Fail if They Are Not Followed!

- Auditing your SOPs — strategies for determining if staff are following procedures
- Integrating SOPs and detailed audit checklists
- Red flags or trigger points that the FDA looks for in SOP compliance and training
- Cooperative strategies to enforce your procedures

12:00 P.M. – 1:00 P.M. LUNCH

1:00 p.m. – 2:30 p.m. Class Project

- Top strategies for determining SOP needs — there's usually more than meets the eye
- Gap analysis of how your current workflow processes may be contributing to deficiencies in existing SOPs
- SOP system and library management
- INTERACTIVE EXERCISE! How to apply the learned techniques to specific operations. You'll take home a well-honed SOP on your toughest procedure

Effective SOPs

into a Collaborative Success

- Durham Airport/Brier Creek, Raleigh, NC

YOUR EXPERT INSTRUCTOR



David R. Dills, Regulatory Affairs & Compliance Consultant currently provides regulatory affairs, compliance and quality consultative services for early-stage and established Class I/II/III device, In Vitro Diagnostics, and bio/pharmaceutical manufacturers on the global landscape, and also has an accomplished record with more than 24 years of experience in the areas of Regulatory Affairs, Compliance and Quality Systems. He has been previously employed, with increasing responsibilities by medical device manufacturers and consultancies, including a globally recognized CRO and has worked directly with manufacturers engaged in compliance remediation activities and services involving consent decrees, CIA's, warning letters, 483 observations, and customer generated compliance events.

Mr. Dills has authored and published validation, regulatory and compliance-related articles, commentaries and technical guides, and is an accomplished global industry presenter. Mr. Dills' academic degrees include Environmental Science and Biology. He is a former Chair and Co-Chair of ASQ's Section 1506 and associated with the Biomedical Division, RAPS, AdvaMed, PDA, ISPE, and other industry working groups.

WHO SHOULD ATTEND

Whether you're a novice or experienced professional, you'll find this unique roll-up-your-sleeves and dig-in workshop exactly what you need if you're involved in the drug, biologics, device or diagnostics industries. Anyone associated with writing and enforcing SOPs will call this the go-to workshop of the year.

COURSE BINDER MATERIALS

- Guidelines for Auditing or Assessing Your SOPs
- Samples of Templates for SOPs
- Flow Chart Example for SOP Development and Implementation
- Current FDA Requirements and Regulations
- Recent FDA 483 and Warning Letter Citations Relates to SOPs
- Best Practices for Writing and Enforcing SOPs
- Training Tips to Ensure Personnel Comply With Your Procedures
- SOP Commentaries/Articles as a Supplement to Addressing Compliance Expectations
- Best Practices in Document Format and Organization

"David was very knowledgeable and presented the information in a clear and effective manner. He was very passionate about the subject making it a very enjoyable and exciting experience. His presentation was thoughtful and detailed. It put things in a whole new perspective for me. Great job!"

Rachael Cartier, QA Associate,
Bionique Testing Laboratories

FDANEWS

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LOCATIONS AND HOTEL ACCOMODATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **FDAnews** workshop to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. The hotel may require the first night's room deposit with tax. Room cancellations within 72 hours of the date of arrival or "no-shows" will be charged for the first night's room with tax.

LODGING AND CONFERENCE VENUE:

July 17-18, 2014

Embassy Suites Raleigh - Durham Airport/Brier Creek

8001 Arco Corporate Drive

Raleigh, NC 27617

Toll Free: (800) 362-2779

+1 (919) 572-2200

www.RaleighDurhamAirportBrierCreek.EmbassySuites.com

Room rate: \$159 plus 12.75 percent tax

Reservation cut-off date: June 30, 2014

TUITION

Tuition rate is \$1,797 per person and includes all workshop sessions, workshop materials, two breakfasts, two luncheons and daily refreshments.

CANCELLATIONS AND SUBSTITUTIONS

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund — less a \$200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days of the start date of the event. A credit for the amount paid may be transferred to any future **FDAnews** event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that **FDAnews** cancels the event, **FDAnews** is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

TEAM DISCOUNTS

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Call (888) 838-5578 for details.

FOUR EASY WAYS TO REGISTER

Online: www.SOPsWorkshop.com

Fax: +1 (703) 538-7676

Phone: Toll free (888) 838-5578 (inside the U.S.)
or +1 (703) 538-7600

Mail: **FDAnews**, 300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 USA

YES! I want to attend **Creating Effective SOPs on July 17 -18, 2014.**
I understand the fee of \$1,797 includes all workshop sessions, workshop materials, two breakfasts, two luncheons and daily refreshments.

FDANEWS

300 N. Washington St., Suite 200
Falls Church, VA 22046-3431

(Please see "Team Discounts" above for tuition discounts when you send a team of three or more.)

Attendee 1: Name _____ Title _____ Email _____

Attendee 2: Name _____ Title _____ Email _____

Attendee 3: Name _____ Title _____ Email _____

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization _____

Address _____

City _____ State _____ Zip _____

Country _____

Phone _____ Fax _____

Payment Options

Check enclosed, payable in U.S. funds to FDAnews

Charge to: Visa MasterCard American Express

Credit card no. _____

Expiration date _____

Total amount \$ _____

Signature _____

(Signature required on credit card and bill-me orders.)

Print name _____

Bill me/my company \$ _____

Purchase order # _____

(Payment is required by the date of the conference.)