During this workshop, you will not sit back and passively listen to a lecture.

Instead, you will be divided into teams, and through case studies, role playing, real-life examples, and exercises, you'll discover how to ensure that your written correspondence reflects your compliance initiatives.

Nov. 13–14, 2013 • Doubletree Bethesda Hotel • Bethesda, MD

FDA Recordkeeping, Dangerous Documents and Writing for Compliance™

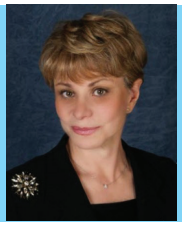
It's no longer enough to set up an effective FDA documentation program. Thanks to product liability lawyers, documentation also needs to be defensible … from criminal actions as well as lawsuits.

Learn what you need to know about establishing and maintaining an FDA-compliant documentation system, including:

- How to analyze your audience(s) to obtain the proper tone and voice for the writing
- What one basic writing structure should be applied to all CAPA investigations
- The role of technical information within a document, and how this information should be presented

John Avellanet
Managing Director & Principal
Cerulean Associates LLC

John (Jack) Garvey
Founder
Compliance Architects LLC



Nancy Singer
President
Compliance-Alliance LLC
Former Attorney,
US Department of Justice

FDANEWS

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WORKSHOP AGENDA

DAY ONE

8:30 A.M. – 9:00 A.M. REGISTRATION AND CONTINENTAL BREAKFAST

9:00 a.m. – 10:00 a.m. FDA Records & Documents: What's Really Required?

- Key provisions of the law.
- Buried requirements in the regulations.
- Guidances — what you don't know will hurt you.
- Warning letters — more hidden requirements!
- Exercise: Attendees determine if a recordkeeping statement is a hidden regulatory requirement.

SPEAKER: **JOHN AVELLANET**

10:00 a.m. – 10:30 a.m. FDA's Hidden Agenda for Record Integrity

- FDA inspections — questions FDA investigators ask to find gaps in your documents and untrustworthy records.
- FDA warning letters analysis
- FDA enforcement actions — who has the FDA prosecuted and enjoined?
- FDA concerns — digital v paper records.
- Exercise: Attendees act as FDA investigators in three different case studies.

SPEAKER: **JOHN AVELLANET**

10:30 A.M. – 10:45 A.M. BREAK

10:45 a.m. – 11:10 a.m. Dangers of Working in the Drug and Device Industry

- Why firms are subject to scrutiny.
- **Role play** — Techniques that lawyers and third parties use to twist the meaning of words.
- Who in a company can be held criminally liable for failure to comply with requirements?
- How will the FDA determine who is responsible for which activity?
- **Self-analysis** — Attendees determine their personal exposure.

SPEAKER: **NANCY SINGER**

11:10 a.m. – 12:00 p.m. Company Communication: Who's Reading Your Documents?

- Are your documents communicating what your reader needs to know?
- Points to consider when writing documents for internal audiences.
- Exercise: How employees get burned when writing documents for external audiences.

SPEAKER: **NANCY SINGER**

12:00 P.M. – 1:00 P.M. LUNCH

1:00 p.m. – 1:30 p.m. Records as Evidence – How it Can Help or Hurt You

- Exercise: Differentiating between facts and opinions.
- Who should write opinions on regulatory issues and who should stick to the facts.
- **Role play** — How informal opinions can be introduced as evidence.

SPEAKER: **NANCY SINGER**

1:30 p.m. – 2:00 p.m. Creating Documents That Will Tell the Company's Compliance Story

- Exercise: Distinguishing between supported and unsupported statements
- Complaints — capturing key information.

SPEAKER: **NANCY SINGER**

2:00 P.M. – 2:15 P.M. BREAK

2:15 p.m. – 3:00 p.m. Creating Documents that Tell the Company's Compliance Story (continued)

- CAPA — the information that FDA wants to see in your files.
- Writing documents in the active vs the passive voice.
- Exercise: How to write meeting minutes.

SPEAKER: **NANCY SINGER**

3:00 p.m. – 4:00 p.m. What to Toss, What to Keep and For How Long

- Brief review of a retention schedule tool.
- Process for sorting through warning letters to find hidden requirements on how the FDA wants you to keep your records.
- Understand what "minimum" retention time really means.
- Exercise: How to prepare an FDA records retention schedule.

SPEAKER: **JOHN AVELLANET**

4:00 p.m. – 5:00 p.m. SOPs and Policies: Understanding Exactly What the FDA Wants to See for "Records as Proof"

- Identifying records in every SOP.
- Good recordkeeping practices.
- Long term archival and destruction.
- Exercise: Review an SOP to find the proof an FDA investigator would expect to see if the SOP were followed.

SPEAKER: **JOHN AVELLANET**

DAY 2

8:30 A.M. – 9:00 A.M. CONTINENTAL BREAKFAST

9:00 a.m. – 10:00 a.m. Sponsors, Purchasers, and Supplier Records — What to Include

- Records required to demonstrate oversight.
- Supplier dossiers — the records of supplier oversight that the FDA expects to see under FDASIA.
- Dealing with data integrity/Part 11 at supplier.
- Exercise: FDA recordkeeping questions to ask your critical suppliers.

SPEAKER: **JOHN AVELLANET**

10:00 A.M. – 10:15 A.M. BREAK

10:15 a.m. – 11:00 a.m. What to do When You Encounter Inappropriate Documents

- The problems with CYA memos.
- Exercise: What to do when you receive an inappropriate email.
- **Discussion:** How to handle situations wherein you disagree with the opinion of your manager.

SPEAKER: **NANCY SINGER**

11:00 a.m. – 11:30 a.m. Email and Social Media: The Unrecognized Threat

- Exercise: The dangers of writing personal emails at work.
- How companies have gotten burned with inappropriate emails.
- Lessons learned from the inappropriate use of social media.
- Exercise: Words to avoid.

SPEAKER: **NANCY SINGER**

11:30 a.m. – 12:00 p.m. How to Design a Program for Good Documentation Practices

SPEAKERS: **NANCY SINGER AND JOHN AVELLANET**

12:00 P.M. – 1:00 P.M. LUNCH

1:00 p.m. – 2:30 p.m. Writing for Compliance™, Part 1: Background & Basics

- The Problem of Poor Writing in FDA-Regulated Industry.
- Exercise Session 1: Product Release Decision.
- The Basics-Focus on the Fundamentals/ Writing Tips/Concepts.
- Exercise Session 2: Regulatory Submissions.

SPEAKER: **JACK GARVEY**

2:30 P.M. – 2:45 P.M. BREAK

2:45p.m. – 4:15 p.m. Writing for Compliance™, Part 2: Unique Aspects, CAPA, and Tools, Methods and Approaches

- Unique Characteristics of and Challenges in Writing for Compliance.
- Exercise Session 3: FDA483 Response Letter.
- Unique Characteristics of and Challenges in Writing for Compliance (part 2).
- Exercise Session 4: Consumer Complaint Investigation Technique.

SPEAKER: **JACK GARVEY**

4:15 p.m. – 4:30 p.m. The Path Forward and Q&A

SPEAKERS: **NANCY SINGER, JOHN AVELLANET AND JACK GARVEY**

4:30 P.M. WORKSHOP CONCLUSION

uments and Writing for Compliance™

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WHO SHOULD ATTEND

- Regulatory Affairs
- Quality Assurance/Quality Control
- GMP Technical/Operations Management
- Engineering and Design Control Teams
- Legal and Compliance Officers
- Clinical Research Directors
- Executive Management

WHAT FIRMS WILL BENEFIT

- Drug companies
- Biotech companies
- Device companies
- Diagnostics companies
- Supplement/Cosmetics companies
- Food companies
- Tobacco companies
- Others regulated by the FDA

ONE-OF-A-KIND TAKE-HOME RESOURCE EXCLUSIVELY PROVIDED TO ATTENDEES

All attendees will receive a flash drive that includes the following:

CHECKLISTS/WORKSHEETS

1. Checklist: A 27-Point FDA Recordkeeping Compliance Self-Assessment
2. An 11-Step Quick Guide to Implementing an FDA-Compliant Recordkeeping Program
3. A 6-Minute Weekly FDA Records Review "Cheat Sheet"
4. Checklist: Maintaining Defensible Complaint Records
5. Checklist: Practices that Will Cause Documents to be the Source of Major Problems in Company Files
6. Checklist: Example Supplier Qualification and Monitoring Records to Retain
7. AdvaMed Points to Consider When Preparing for An FDA Inspection Under the QSIT Corrective and Preventive Action System
8. Nine Dangerous Words that Attract the Attention of FDA, Prosecutors and Product Liability Lawyers
9. A 9-point checklist of proofreading suggestions designed to eliminate 99% of your errors

POLICY/FORMS

1. Policy: Good Documentation and Recordkeeping Practices
2. Form: FDA Required Record Destruction Form
3. Form: FDA Archived Record Issue & Retrieval Log

ARTICLES

1. Article: "*Don't Be Haunted By Your Words*"
2. Article: "*Building Workplaces Where Documents Reflect Compliance Initiatives*"
3. Article: "*How to meet FDA Recordkeeping Requirements*"

OTHER

1. FDA's own records and document control SOP

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:

Nov. 13-14, 2013
Doubletree Bethesda Hotel
8120 Wisconsin Avenue
Bethesda, MD 20814
Toll free: (800) 560-7753 • Tel: +1 (301) 652-2000
www.doubletreebethesda.com
Room rate: $179 plus 13% tax
Reservation cut-off: Oct. 21, 2013

TUITION

Tuition of $1,797 includes all workshop sessions, workshop written 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.FDARecordkeeping.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 ***FDA Recordkeeping, Dangerous Documents and Writing for Compliance™*** on Nov. 13–14, 2013 in Bethesda, MD

I understand the fee includes all workshop sessions, workshop written materials, two breakfasts, two luncheons and daily refreshments.

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

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