

Introducing Writing for Compliance[®]

**A Breakthrough Training Workshop Focused on
Improving FDA Inspection Outcomes By
Improving the Quality of Inspected Documents**

Offered exclusively by:



What is Writing for Compliance®?

- A fast-paced training workshop program designed to **improve writing skills** for FDA-regulated industry staff and management, particularly those in quality, operations and related functional areas.
- A training program that **focuses on what FDA Investigators want** from industry's documents, and helps to train staff and management on how to develop documents that will meet those expectations.
- An interactive program, designed specifically for adult learners, that **introduces critical thinking skills** to the review and analysis of quality records and associated compliance documentation.
- A training workshops **helps companies achieve improved FDA inspection outcomes** through better documents.



Why Was the Program Developed?

- To help industry personnel who were never trained in writing fundamentals or considered writers, and who are now in positions where writing reviewing, and approving documents are **essential** skills.
- To address gaps seen from extensive experience with FDA inspection failures where the negative outcome was attributable...
 - *NOT* to bad CAPA investigations
 - *NOT* to failing to follow SOPs
 - *NOT* to failure to try and address complaint trends
 - *NOT* to lack of manufacturing control
 - *NOT* to failure to resolve problems effectively

... but rather to a lack of ability to effectively document and convey appropriate activities and practices in a manner that FDA Investigators can understand ***without significant questions or concerns.***
- To address clear deficiencies in compliance-implicated records and documents whereby the documents fail to describe activities undertaken or meet the regulators requirements and expectations.

Main Program Sections

1. THE PROBLEM

2. RECOGNIZING
DEFICIENT
DOCUMENTS



3. DEVELOPING
COMPLIANT
DOCUMENTS

4. CAPSTONE
EXERCISE

Individual & Team Exercises

1. Identifying Problem Writing
2. The Importance of Context
3. Representing Data
4. Critique Actual Industry Documents; Apply the W4C™ Rubric; Identify W4C™ Steps
5. Capstone Exercise:
 - a) Practice Writing a Document that follows W4C™ Process
 - b) Analyze Practice Documents for Effective Communication

Writing for Compliance® — A National Issue

RANBAXY

Why Good Writing is Difficult

- Insufficient time (and/or skills) to create

Warning Letter
GeoTec, Inc.
September 2015

In the Front Room...

An Aggregation of Writing Styles

Technical Expository

Analysis: Representation of Data Investigation and/or Analysis

Data are unbiased ...
Which value is larger?

20 ppm or 0.002%

Analysis: Representation of Data / Information Investigation and/or Analysis

Context Qualification Tone Chart Scale / Chart Type Arrangement Modifiers

DATA & INFORMATION

WRITING FOR COMPLIANCE®

BETTER DOCUMENTS • IMPROVED OUTCOMES

Faculty / Instructors



John C. (Jack) Garvey, Esq.

Experience:

- ✓ 25+ years in FDA-regulated operations, quality, compliance, regulatory and law
- ✓ Founder & Principal, Compliance Architects LLC

Education:

- ✓ Chemical Engineer / Attorney

Focus Areas:

- ✓ Enforcement remediation
- ✓ Quality System Architectures
- ✓ Corporate Compliance
- ✓ HACCP / process mapping & risk analysis
- ✓ CAPA program development
- ✓ Computer-based systems, enterprise risk management and quality operations
- ✓ Inspection readings and preparation



Deborah Lydick

Experience:

- ✓ 25+ years in Medical Device quality, compliance, operations, laboratory management
- ✓ President, Catalyst Advantage Group LLC

Education:

- ✓ Laboratory Technology, Management, Strategic Leadership

Focus Areas:

- ✓ Training design and training systems
- ✓ Organizational / cultural change
- ✓ Quality system improvement
- ✓ Process analysis and improvement
- ✓ CAPA process improvement
- ✓ Auditing and audit readiness

Course Feedback Metrics

Scale of 0 to 10 (0 = worthless; 5 = average; 10 = excellent)	
Overall Workshop Rating:	8 or higher: 80% 9 or higher: 39% Perfect 10: 23%
"Relevant to the Work You Do?"	94%
"Would You Recommend to a Colleague?"	95%

Over 200 Attendees to Date From:

- Allergan Medical
- Becton Dickinson
- ConvaTec
- Haemonetics
- Terumo
- Johnson & Johnson
- West Pharmaceutical Company
- Medtronic
- Philips Healthcare
- Janssen Diagnostics
- Church & Dwight
- Fresenius Medical
- Dupont
- Qiagen
- Covidien
- Nordion
- Novo Nordisk
- Novartis

Attendee Comments

- Very good course....
- It is excellent tool for QA site managers and VPs of QA.
- Presentation had clear, plain language – perfect. ... Great session.
- Good Program....
- Great job! Very thorough. Good examples. Inspire passion on writing with blend of compliance and science. Useful concepts. Timely and valuable.
- Good course. ... I would recommend it to most of my company.
- Speaker was very good and knowledgeable.
- Well organized. Speaker was engaging and presented topics in a thorough way.
- The concept of tying the workshop to specific [company] examples was bang-on.
- A good investment of my time today.

I thought it was outstanding. ...
10s all the way.

Questions?

For further information, please:

- ✓ Call us at 888-734-9778
- ✓ Contact us at w4C@compliancearchitects.com; or
- ✓ Visit writingforcompliance.com