

## **Dangerous Documents:**

*Avoiding Land Mines in Your Emails and Documents*  
*Thursday, September 16, 2010 (8:30 a.m. – 12:30p.m.)*  
*Hotel Du Pont, Wilmington, DE*

### **The Problem:**

"Land mine" is a term we use for something buried in your company that will blow up if it is uncovered. In court, even an innocuous phrase in a private email from one of your employees, such as, "This will negatively impact the bottom line," could be a land mine. In a product liability action, a plaintiff's lawyer could use this statement to undermine the credibility of your organization.

When was the last time you cringed after reading an email sent by someone in your organization as you imagined how a prosecutor or plaintiff's lawyer could use it to imply sinister behavior? Maybe it was just last week or last month. It's not that your employees don't care, it's just that they don't know.

Every day thousands of emails are sent by your server, which because of technology, can be retrieved indefinitely. As we say, **documents are like diamonds - they are very precious and they last forever.**

To survive in our litigious society, organizations need to have the right communications culture. Everyone needs to understand what they should, or should not, write in their emails and other documents.

Cases in point: Guidant, Bayer, Merck, Eli Lilly, and American Home Products were sued. During discovery, they were forced to produce their employees' emails and other documents that they thought were confidential. These documents contained inflammatory statements that embarrassed the companies and forced them to enter into expensive settlements. Don't let this happen to your firm. All of your employees must know how to write emails and other documents that are complete and accurate and do not create land mines.

### **The Solution:**

EduQuest has teamed with Compliance-Alliance to offer this special half-day course to train your employees and reduce your risks. ***Dangerous Documents: Avoiding Land Mines in Your Emails and Documents*** is an

interactive educational program. By participating in the program, you will discover the potential consequences of writing emails and other documents that are inappropriate. You will learn to create correspondence that, if subpoenaed, will demonstrate your firm's commitment to quality and regulatory compliance... instead of exposing costly and embarrassing surprises.

*Dangerous Documents* has been presented at leading corporations such as Medtronic, Siemens, and Allergan. The course has also been delivered as part of the Masters program at the University of Southern California and at several compliance symposia at Harvard University. Participants' reactions have been overwhelmingly positive. Engineers and software developers have said the course is so valuable that they wished it had continued longer than four hours.

### **Course Content:**

Here's some of what you will learn at *Dangerous Documents*:

- Who can be held criminally liable under the Federal Food, Drug and Cosmetic Act
- What FDA investigators look for when reviewing documents
- The risks of leaving blanks and using white-out in required records
- How to write informative documents that don't make you a target
- How to distinguish between fact and opinion
- 8 common practices that are sure to get you in trouble
- Why you need to document your risk management activities
- The dangers in not monitoring employees emails
- 4 types of information never to include in documents
- 18 words that will attract the attention of prosecutors or plaintiff's lawyers
- Why it is crucial to follow a document retention program
- How to write a memo that will be read and acted upon
- How to build a program to avoid dangerous documents

### **About Your Instructor:**

Nancy Singer (former prosecutor and defense attorney) founded Compliance-Alliance LLC to specialize in professional development for those employed in drug, device and other manufacturing industries. She

created the course, "Dangerous Documents" when she was employed as General Counsel for a drug and device firm. While reviewing documents, she noticed that the employees at her firm failed to understand how a plaintiff's lawyer could use their emails and other documents to the firm's detriment if the firm was ever sued in a products liability action. She presented the course to her colleagues. The response was uniformly positive. She then took it to other firms, universities and industry meetings.

Singer's career began as an attorney with the United States Department of Justice where, during a three year period, she successfully prosecuted seven firms for violations of various criminal statutes. Subsequently she was a partner at the law firm of Kleinfeld, Kaplan and Becker. Singer received her B.S. from Cornell University, and J.D. and LL.M. degrees from New York University Law School. During her career she was an instructor at Catholic University Law School, George Washington University Law School, University of Southern California, and at compliance symposia at Harvard University. She received Vice President Gore's Reinventing Government Hammer Award, the FDA Commissioner's Special Citation, and the Food and Drug Law Institute's Distinguished Service and Leadership Award. Singer is a retired Commander in the United States Naval Reserve.

### **How to Register:**

1. Call 301-874-6031 and charge your tuition investment of \$495 to a major credit card, or
2. Visit [www.EduQuest.net](http://www.EduQuest.net) and download the Course Registration Form.
3. Mail your check payable to EduQuest to EduQuest, 1896 Urbana Pike, Suite 14, Hyattstown, MD 20871, USA

### **What People Are Saying about the Dangerous Documents Course:**

MEDTRONIC

"I learned techniques to address issues in a positive way, so they do not become bigger issues."

- *Gail Block, Project Manager, June 27, 2008*

"This interactive course used good examples and made me more aware of the potential issues that can arise with documentation."

– *Catherine Perrone, Senior Regulatory Affairs Specialist, November 18, 2008*

"I now will be more careful about how I will state things in my emails."

– *Sally Quest, Buy Planner, November 18, 2008*

"I will write fewer emails and use more direct communication."

– *Al Beatrez, Commercial Release Manager, November 18, 2008*

"I will not leave blanks in forms."

– *Stephanie Elhard, Senior Safety Manager, November 18, 2008*

"I will rethink sending personal emails."

– *Teresa Peterson, Buyer Planner, November 18, 2008*

"This course increased my awareness and I will take time to reread my emails before I push the send button."

– *Jan Dugas, Regulatory Trainer and Compliance Specialist, November 18, 2008*

"I will look at what I write from an outsider's perspective who is trying to tell a story."

– *Jenn Dolan, Technical Sourcing Specialist, November 18, 2008*

## SIEMENS

"I will pay more attention to non-project related documents."

– *Jim Wade, Systems Engineer, May 20, 2008*

"I will use more precise and objective words."

– *Aiying Sun, Manager Quality System Validation, May 20, 2008*

"I appreciated the exercises and the instructor's ability to make people participate." - *Jorge Bohorquez, Applications Specialist, May 25, 2008*

"I enjoyed the interaction as this provided a different way of looking at the same situation."

– *Ramin Nekouka, Senior Manager Technical Siemens, June 20, 2008*

"I will be more mindful of my word selections in emails, text messages and other documentation."

– *Myrtis Randolph, Clinical Application Tester, June 25, 2008*

## ALLERGAN

"The course was very different than other training we have had. It was very informative and provided great information all compiled in one place."

– *Mirshshemi Sahba, QA/QC Director, June 5, 2008*

"Very interactive and thought provoking."

– *Lisa Carroll, QA Manager, June 5, 2008*

"Very pertinent to our work."

– *Teresa Kuan, Manager WWQA, June 5, 2008*

"Pragmatic and animated."

– *Pasaf Chanton, Assistant Director European Quality, June 5, 2008*

"Great group interaction."

– *Lilly Tu WWQA VP Biologics, June 5, 2008*

"I wish it were longer."

– *Ava Yap, QA Manager, June 5, 2008*

## MASTERS DEGREE PROGRAM AT THE UNIVERSITY OF SOUTHERN CALIFORNIA

"This was very informative. It was lots of fun and an exciting way to learn."

– *Mahek Lamphriya, student in the MS program, July 13, 2008*

"I now will think before writing and think before sending."

– *Yi Zhao, Reseach Assistant Professor, USC, July 13, 2008*

"I will treat emails more formally."

– *Phyllis Tai, Post Doctoral Fellow, USC, July 13, 2008*

"I now understand the importance of documenting and writing things correctly."

– *Rajas Chadanker, Post Doctoral Fellow, USC, July 13, 2008*

"The program was lively, interactive and informative."

– *Michelle Chu, Quality Engineer, July 13, 2008*

"I enjoyed the learning activities and I will use the communication and diplomatic skills."

– *Ankit Shah, MS, BME, July 13, 2008*

#### COMPLIANCE SYMPOSIA AT HARVARD UNIVERSITY

"I enjoyed the examples provided, and hearing from the other participants."

– *Steven Klingerberg, Validation, Baxter Healthcare, August 21, 2007*

"I appreciated the willingness to entertain attendees' opinions during the course."

– *Steven Johnson, Vice President and General Counsel, Allergan, August 21, 2007*

"It was helpful to learn about the interrelation of documentation and legal proceedings."

– *Garry Heidel, Director Regulatory Compliance, Alcon, August 21, 2007*

"I appreciated the basic tips to improve my writing skills."

– *Snad Thele, Senior Manager Business Practices, Merck, August 21, 2007*

"Great presentation; useful examples."

– *Henry Wroblewski, Regulatory Affairs, Bayer Healthcare, August 2007*