



American Society for Quality (www.asq.org) – Washington D.C. and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group Meeting

“Dangerous Documents: Avoiding Land Mines in Your FDA Record and Emails”

Presented by

Nancy Singer, JD, LLM

President, Compliance Alliance

October 29, 2009 (Thursday) Evening

6:00 PM – Networking and Pizza and soft drink with a door prize

6:20 – 8:50 PM – Program (a break at 7:30 pm)

8:50 – 9:00 PM – Door-prize drawing and networking

Open and free to the public

Location:

Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

Driving directions:

From I-270 (N or S bound):

Take Exit 9A and exit from the first right exit.

Turn left (east) onto Shady Grove Dr.

Turn right (south) onto Rockville Pike (**Route 355**).

Turn left (east) onto East Gude Dr.

Turn left (north) immediately onto Crabb's Branch Dr.

Turn left (west) immediately onto Standish Place.

(The first building on your right side is 7519 Standish Place; open parking)

The conference room is on the first floor with its entrance opposite to the left side of building main entrance.

For headcount purpose, please register by Thursday noon, Oct. 29, 2009.

Registration Website: <http://www.asq509.org/ht/d/DoSurvey/i/35817>

For registration problems or further information contact **Dr. George Chang**, Co-Chair of

Biomed/Biotech SIG, at gchang2008@yahoo.com or call **240-793-8425**.

Presentation Summary:

Dangerous Documents: Avoiding Land Mines in Your FDA Records and Emails

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. During this interactive session, attendees will learn how lawyers can take sentences from memos and emails out of context and have them imply inappropriate conduct.

Specifically this session will cover:

- Who can be held criminally liable under the law
- 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
- The dangers in not monitoring employees emails
- Types of information never to include in documents
- Words that will attract the attention of prosecutors or plaintiff's lawyers
- Why it is crucial to follow a document retention program
- How to build a program to avoid dangerous documents

Speakers' Bios:

Nancy Singer, JD, LLM (nancy_singer@juno.com)

Nancy Singer 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.