

MTLI/Compliance-Alliance

Setting Up a Program to Avoid Dangerous, Damaging Documents

Wednesday March 24, 2010

1:30 pm **Welcome: Tom Maeder, Executive Director, MTLI**

1:40 pm Nancy Singer (former prosecutor and defense counsel) will use case studies, hypothetical problems and benchmarking exercises to demonstrate the importance of good documentation practices. The participants are divided into groups. After hearing each stage of the instructional program, they analyze improperly written documents and revise them to reflect the firm's commitment to quality. Specifically, participants:

- Find out who can be held criminally liable under the law
- Learn what FDA investigators look for when reviewing documents
- Examine warning letters where the government has cited firms for poor documentation
- Discover the risks of leaving blanks in required records
- Analyze a series of statements to determine which are facts and which are opinions
- Learn when to avoid writing opinions on FDA regulatory matters
- Discuss the dangers in not monitoring employees' emails
- Practice substituting less harsh words for inflammatory ones
- Find out why it is crucial to follow a document retention program
- Rewrite sentences that, when taken out of context, appear to be inflammatory
- Read inappropriate emails from employees of Guidant, Merck, Bayer, Chevron, Arthur Andersen, and Microsoft that were reported in the media
- See how the former NY Attorney General used carelessly written documents
- Develop a plan to implement a program to avoid dangerous, damaging documents

5:00 pm Adjournment

