Building Workplaces Where Documents Reflect Compliance Initiatives

By Nancy Singer, JD, LL.M

Medical device and pharmaceutical companies make thousands of products that save or improve the quality of lives. Although these products can and do help people, they can also be ineffective or potentially harmful. Employees working for these firms have a strong sense of mission. They are genuinely good individuals who want to make a difference, manufacture safe and effective products and follow the law.

The US Food and Drug Administration (FDA) has detailed regulatory requirements for designing, manufacturing and marketing healthcare products. Companies are required to create standard operating procedures (SOPs) explaining how their firms set up systems to comply with requirements, and then document that employees adhered to those procedures. The companies generally assign these tasks to regulatory and quality assurance (QA) professionals who understand the importance of accurate documentation. Part of the regulatory QA professionals jobs is to educate his or her colleagues on the need for company records to be filled out completely, and signed and dated on the day an activity actually occurred.

During an inspection, an FDA investigator will only view documents. The agency's position is that if an action is not documented, it did not happen. If a company's records are not complete, the investigator will cite the company as being deficient in an official inspection report on Form FDA 483. If FDA finds that the company had numerous deficiencies, the agency can send the company a Warning Letter or institute other forms of regulatory action.

Employees working for companies that manufacture and market healthcare products need to understand that their activities are constantly under a microscope. If a patient is injured, or a company manufactures or distributes unsafe or ineffective products, various entities will behave like sharks, ready to attack the company.

For example, the competition wants to steal the company's market share. Federal prosecutors want to see if the company failed to comply with regulatory requirements and, if so, make an example of it. State prosecutors want to ensure that the company followed all local requirements. If it does not, the company can be assessed large fines to make up budget deficits. Also, plaintiffs' attorneys want to obtain large monetary awards for their clients. Finally, the media often look for negative stories to write about the company.

The Problem

The recession, competition from overseas markets and increased regulatory requirements are factors forcing employees to do more work in less time. Employees running late for a meeting, or interrupted by a phone call can accidentally omit important information in a document. Additionally, frustrated by unexpected network breakdowns or power outages, they may write blunt comments on sticky notes, cryptic emails using inflammatory words, or reports that may not contain all the required information. Most of the time, these documents just remain in the file. However, if a patient is injured by one of the company's products, other parties may gain access to the company's records.

Specifically, FDA could increase its oversight by initiating an immediate inspection or request for more documents during the regularly scheduled inspection. The company could be sued in a product liability action, and then the plaintiff's lawyer would gain access to the company's records. The plaintiff's lawyer will examine the documents to see if he or she can find a statement that might be used to infer inappropriate conduct.

In court, documents speak for themselves. Federal prosecutors can introduce company records as evidence to show that a company distributed products that were not manufactured according to FDA's regulatory requirements. This could subject both the company and the employees to civil or criminal penalties. Plaintiffs' lawyers can use the documents to show that the company's action violated the law, and that the company was negligent or even reckless.

Most corporate interpersonal communication is done by email. Many people, thinking email is private, believe they can be more open. They are wrong. Emails can be considered official documents. Inflammatory terms, incomplete material, missing dates or postdated forms can cause serious problems. The following situations would also be cause for concern in the workplace:

- people writing personal unsupported opinions on issues for which they do not have authority or responsibility
- reports containing inappropriate rationales for why an activity complies with a regulatory requirement
- short emails or statements that are imprecise or do not contain all of the facts
- minutes from meetings reflecting who said what
- handwritten notes on documents

How Should the Problem Be Solved?

Top management must accept that this is a problem. The corporate culture needs to change so that every employee knows that he or she is an ambassador of the firm. They should feel confident that all written communication will reflect the practice of making safe and effective products that comply with all applicable government regulations. Below is a six-step program that will accomplish this goal.

Step 1: Include Appropriate Communication as a Core Value

Top management should review the company's core values to ensure that appropriate communication is included as a practice to which all employees should adhere.

This expectation should be posted on the company's internal website or intranet. The corporate handbook should emphasize that all material written on company computers is the property of the company. Regulatory and QA professionals should institute a program to review SOPs to make sure that they reflect employee practices. Finally, all employees need to commit to following them, not just having them in a binder.

Step 2: Define Expectations and Change Job Descriptions

Management should define the company's expectations and tie the new written communications policies to individual performance reviews.

For example, if employees do not have regulatory authority for specific matters, they should not be injecting personal, unsubstantiated opinions into official reports and records. These employees should share their thoughts, insights and creative solutions in meetings rather than sending dogmatic memos on the subject. Meeting minutes should reflect the reasons for outcomes and results rather than who said what.

Step 3: Educate Employees on Professional Communication.

The regulatory and QA professionals should take the lead in organizing a series of training sessions where all where employees in the company can learn how to write facts, discuss issues and describe actions in a clear way so that the individuals' statements will not be misinterpreted.

Having a lawyer with trial experience conduct the training is a useful strategy. This individual will have credibility and will truly understand how vague or cryptic documents can be used to imply inappropriate conduct.

In putting the training sessions together, the Regulatory and QA professionals should recruit the cooperation and assistance of key company department heads. The department heads can require that employees under their supervision attend one of the sessions, and they can help the lawyer present the content. This sends a strong message that management endorses the program.

The training should not have a lecturer stand in the front of the room reading bullet points from PowerPoint slides. Instead, the training should actively involve all participants in the discussion. The speaker needs to be dynamic and capable of holding an audience's attention.

Techniques to keep everyone engaged include analyzing company documents from the perspective of an FDA investigator or a plaintiff's lawyer. Simulating a trial can be effective, during which volunteers are asked to defend company documents. Exercises in rewriting memos, and the discussion afterward, are also effective teaching tools for improving writing skills.

Another effective method would be to ask the participants to pretend to be witnesses and respond to questioning by:

- the zealous criminal prosecutor attempting to convict a firm of wrongdoing
- an indignant plaintiff's lawyer acting on behalf of someone injured by a firm's product
- a suspicious FDA investigator who is looking for discrepancies from the requirements for which he or she can cite a company
- a skeptical FDA reviewer who needs to determine from a company's application if the data are adequate to allow the firm to market its drugs or devices

During roleplaying, participants learn that lawyers on either side often allow only for yes and no answers with little time to explain in detail. The exercise allows participants to see situations in different ways.

Meanings of terms are fodder for discussion. All employees need to understand the differences between fact and opinion and who within their company would be considered an expert and would be qualified to write an expert opinion on a regulatory issue.

Other techniques include conducting group quizzes about who can be held liable under the *Food, Drug, and Cosmetic Act* and having people explain the consequences of what could happen if procedures are not followed.

The instructor should distribute guiding principles for the use of email and creating good

documentation. Some suggested principles might include:

- Documents last forever.
- People will read your documents with their own agendas.
- If you have authority for regulatory issues or corrective actions, you should provide opinions in writing. If you do not have authority, you should provide the facts to the person who is the decision maker.
- Do not include adjectives with factual statements.
- Provide references to support conclusions.
- Be precise when writing reports.
- Proofread written work by reading it aloud.
- Discuss controversial subjects in meetings rather than through emails.
- Use the phone or communicate in person when written records are not needed.
- Do not send emails when feeling angry.
- Do not use sarcasm in emails.
- Limit using the company email system for personal matters.
- Only provide copies of emails to people who need to know about an issue.
- Do not forward long email chains. People do not want to read them, and they may include inappropriate information.

At the end of the training, the instructor should ask attendees to commit to how they will improve their documentation practices because of the class. Department heads should follow up a few months later, noting improvements and areas still needing work.

Many students taking similar training say they learned how to evaluate their own writing for inflammatory words, allowing some time to pass before writing emails and other types of writing. They also learn to consider the nature of their audience when writing documents.

Step 4: Follow Up After the Training.
The company's management can institute a follow-up program where people collect examples of inappropriate emails or other documentation they received. Identifying information on these documents should be concealed or removed to avoid public embarrassment. Twice a year, each department can hold a training refresher luncheon where people discuss how these documents in the wrong hands could be misinterpreted.

Once a quarter, the company can hold mandatory document clean-up days for the entire staff. On this day, people may come to the office in extreme business casual attire to clear out personal and departmental files of clutter and outdated items. When unsure whether or not to retain items, employees should always check with supervisors. Having a shredder or other document disposal method readily available will help the process.

Other ways to reinforce the message are to display posters, create screen savers or distribute mouse pads with phrases such as "Documents are like diamonds. They are precious, and they last forever."

Regulatory and QA professionals should ensure that, during a company's internal audit, documents that could be misinterpreted are noted. They should take corrective action by encouraging the appropriate person to augment the file with explanatory information, so the situation can be put in context to reflect what actually occurred.

Step 5: Create Procedures for Controversial Issues.
Companies should have procedures for dealing with difficult issues so, when the situation occurs, employees will know what to do.

For instance, if employees have concerns about a product or anything else, the procedure would tell the employee to meet with his or her supervisor about taking corrective action. If the supervisor disagrees and the employee is still unconvinced, the employee should suggest to the supervisor that they go together and talk to people with higher authority or with other disciplines (compliance officers or lawyers) to resolve the issue.

The rationale behind this course of action is if a regulatory decision is endorsed by appropriate functions within an organization, this will ensure that the institution stands behind the decision.

Step 6: Evaluate Performance.
Managers need to follow up, praising or citing people in their performance reviews for how they write. Workers and managers should develop training plans together that would best meet individual or group needs, such as seminars or business writing workshops, for employees needing further guidance.

Conclusion

Companies that manufacture medicines and devices produce inherently risky products. They are not immune to product liability lawsuits. If the program for improving written communications is put in place, employees will be more aware of expectations and better equipped to take ownership of what they include in documents. They will be held accountable for their *actual* behavior, not what others think they did through poorly written emails, memos or other imprecise documents.

Author
Nancy Singer is president of Compliance-Alliance, LLC, a firm that provides training on good documentation practices. 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 JD and LL.M degrees from New York University Law School. Singer is a retired Commander in the United States Naval Reserve. Her email address is nancy@compliance-alliance.com.