COMPLIANCE CORNER

Do The 'Write' Thing For Documents

Some troublesome FDA inspection outcomes can be traced to quality system documents that are poorly written and do not provide agency investigators with a full picture of the company, its processes and its products.

"The first rule of FDA-regulated documentation is that if it's not documented, then it was not done. But a caveat to that is, if documents are not able to be understood by an agency investigator, then you might as well have not created them," says Jack Garvey, CEO of consulting firm Compliance Architects.

Companies "should make a regulator's job easier when he or she walks into a plant, but they make it difficult for the regulator by failing to write good documents," he said.

Instead, "they force investigators to hunt and peck, and that's when investigators go on treasure hunts to look for negative information to build their own narratives," Garvey told "The Silver Sheet."

Poorly written documents that don't address information the agency wants to see allow investigators to control the dialogue and discussion during an audit, he noted.

Because documents are manufacturers' primary mode of communication with FDA, written information must be meaningful and impactful to the agency. This can pose a problem for quality and regulatory professionals who are not particularly adept at writing.

Writing Tips

Find the best writers. "Let's put it this way: If you were going to staff a baseball team, would you put the worst hitters on the roster just because everybody has to play? No. You put the best hitters on the roster and the best fielders," compliance expert Jack Garvey said.

Don't use buzzwords. "Using buzzwords, to me, is pandering. If a product failed, it failed. You shouldn't be afraid to write that. Now, what you do about that failure, though, determines how the agency will perceive your firm. The agency expects transparency. It expects honesty. It expects candor. But it also expects you to understand what's going on, and when something goes wrong, to fix it. Good companies react appropriately and quickly in a controlled manner. When that doesn't happen, companies get in trouble."

Invest in training. "The amount of money that companies spend on compliance remediation is huge. If you can reduce that through a focus on good writing techniques and good communication, the incremental spend would be returned back many times over."

"Quality assurance officials usually have technical backgrounds. A lot of them are scientists. Typically that means they're more oriented toward science and math than writing," Garvey said. "It's a huge disconnect. In industry, people are trained on regulations, trained on procedures - trained on a lot of things. But they don't get trained on how to properly write."

Adequately conveying complex, scientific, technical concepts to a regulator "is a skill. It's an art. And with the money that's left on the table because of substandard inspectional outcomes, it's imperative to do exactly that."

Tell Stories

Manufacturers often fail to include information in documents that tell the agency:

- That the firm knows as much as it possibly can about its device;
- What the product does, how it performs, and what the company does to control the manufacture of its product; and
- Critical steps in device manufacture to display a high level of control.

"Unfortunately, stories aren't being told in documents, in quality manuals, in CAPAs [corrective and preventive actions] and in nonconformance reports about what manufacturers are accomplishing when they're doing all of these activities," Garvey said.

For example, when writing a CAPA, a firm should communicate that a problem happened; that there is a full understanding of what happened; that corrective and preventive actions have been identified; and that the CAPA has been successfully completed.

"That's the basic framework. You have to make sure that you convey to the agency that you have done that in accordance with its expectations," Garvey said.

Nevertheless, some employees that write CAPA reports don't consider what the agency really wants from it, which is a complete, descriptive narrative of what has (and will) happen to the CAPA - that is, an adequate telling of events and not a snappy ten-thousand-foot view.

Ask Questions Before Writing

There are questions that manufacturers should build into their document development and review process, including:

- Are we meeting the regulator's intent?
- Are we addressing the regulator's requirements and expectations?
- Is it easy to understand?
- What will an FDA investigator (or anybody) say about this document 18 months down the road?
- Are we telling our story?

"Those are points that really need to be continually emphasized during the drafting, review and approval process for documents," Garvey said.

Companies should also ask themselves why they are writing a particular document.

"Of course, they know why they're writing it, but *why* are they writing it? There's a difference," Garvey said.

"When it comes to a report of nonconforming product, an employee will think, 'I'm writing this to document a nonconformance.' Well, that's great, but what does 'documenting a nonconformance' mean? What is the agency's objective in the documentation of a nonconformance? What is FDA trying to see?" he said.

"Asking yourself what the agency expects is critically important."