MEDTECH INSIGHT
CITELINE COMMERCIAL

19 Dec 2017 | **Analysis**

Compliance Corner: FDA Wants You To Take These 5 Actions After A Facility Inspection

by Shawn M. Schmitt

US FDA's Sean Boyd says what happens after an inspection is over is just as important as what happens before and during one. Here he lists five critical post-inspection activities that device-makers should keep in mind.

Savvy medical device manufacturers know that a key to surviving US FDA facility inspections is to adequately prepare beforehand to ensure that investigator expectations are met – but even savvier firms make sure they check the box on five critical post-inspection activities, an agency official says.

Sean Boyd, deputy director of the Office of Compliance within FDA's Center for Devices and Radiological Health, said it's important for device-makers to remember that what happens after an inspection is over is just as important as what happens before and during one.

At FDAnews' 12th Annual FDA Inspections Summit in Bethesda, Md., in November, Boyd said companies should take these five actions after the investigator wraps up the audit:

1. Be responsive to inspection observations. "Of course, [problems noted on an FDA-483 inspection form] are just observations. They are not yet violations. They have not yet necessarily been determined to be supportable" by evidence gathered by investigators, Boyd said.

"But providing the information that your investigator requests during the inspection, and addressing things that you know need to be addressed and making that a priority, is certainly important. And if there are things that you can resolve during the inspection itself, certainly those should be resolved so they don't have to be addressed in follow-up to issuance of a 483."

2. Create an action plan with clear timelines and deliverables. "Many firms take advantage of

providing a response to the 483 within 15 days after the inspection. Oftentimes, the issues that are identified are more complex than can be addressed in 15 days, so it's important for you to identify the steps you need to take and the timeline within which you think you can complete those activities, and communicate that to both ORA [FDA's Office of Regulatory Affairs, which conducts all of the agency's field activities] and the device center," Boyd said.

"Once you develop that plan, stick with it. If there are modifications that are necessary because you've learned something that you didn't know a month or two months ago, let us know. Change your plan. Change the timelines and communicate what those new expectations are so we're aware of what to expect throughout our engagement to address these issues together."

3. Provide reasonable and timely updates on progress. "We recognize that not everything can be addressed within a short period of time. Sometimes problems take months to identify, work through, and implement corrective actions," Boyd said. "Tell us where you are in the process. And don't give us more information than is necessary. Just give us the information that's necessary to address the issue and maintain that open line of communication.

"This interaction and the plans that you provide – how adequate they appear to be, and the confidence that we have in your ability to implement and complete those plans – weigh into our decision-making, particularly with respect to the FDA guidance that was published last year regarding benefit-risk."

Finalized in December 2016, that *guidance* outlines a broad framework for considering benefit-risk factors in medical device availability, compliance and enforcement decisions. The document is part of an ongoing effort to harmonize benefit-risk considerations throughout the agency. (Also see "*'A Sea Change': Device Center Compliance Chief Touts US FDA's Benefit-Risk Concepts – But Will Manufacturers Buy In?*" - Medtech Insight, 7 Aug, 2017.)

4. Conduct a systemic review and take systemic corrective actions. "For example, a firm will get an observation that it didn't evaluate a subset of its complaint files for MDR [Medical Device Reporting] reportability. In response to that observation, it evaluates that subset of complaint files for MDR reportability, but the firm doesn't look at its MDR process. The firm also doesn't look at other complaint files to address a potential systemic issue. That's a very frequent thing that we see," Boyd said.

"Or, there could be an observation related to a particular manufacturing process that spans across multiple devices that are manufactured at that site. The firm will fix it for the one device, or the one process or aspect of the process that the investigator observes, but the firm doesn't look more broadly to see the impact on other devices that broadly live in the system.

"Again, it might be a complex issue. It might take more time to address it. But recognizing that

and communicating that is something that we want to see."

5. Provide clear and well-organized responses to FDA. "Sometimes it feels like the agency is getting snowed with too much information, and firms sometimes give us a bin full of procedures and processes," Boyd said. "Prepare a response that identifies: here is the observation; here is the situation surrounding why that observation was noted; here's some background information on the process that's affected; here's the process and the page and the paragraph that we think is a problem; here's exactly how we're going to address it. That allows the FDA compliance officer or the reviewer to get directly to your solution, and it facilitates a much more streamlined or positive interaction between the firm and the agency that's going to allow us to more rapidly recognize what you have done – and what remains to be done."

From the editors of The Gray Sheet