Ready for Virtual FDA Inspections? Agency, Industry Face the Possibility as Pandemic Continues

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As FDA-regulated companies develop and implement plans to restart their operations as COVID-19 pandemic lockdowns ease, four industry experts say that they should add another item to their to-do lists: Get ready for the possibility of virtual inspections conducted by FDA investigators.

During the pandemic, the FDA has been restricted in its ability to conduct facility inspections. On March 10, the agency announced that, due to the pandemic, it was postponing most of its non-U.S. facility inspections except those considered to be “mission-critical,” which would continue to be considered “on a case-by-case basis.” Eight days later, the FDA expanded the moratorium to include inspections conducted in the United States.

The first move toward resuming inspections came on May 11, when the FDA announced that it was working with the Centers for Disease Control and Prevention (CDC) “to develop a process that would govern how and where to return to on-site facility surveillance inspections in accordance with the gating criteria outlined in the White House’s ‘Guidelines for Opening Up America Again.’”

In this process, Commissioner of Food and Drugs Dr. Stephen M. Hahn said, the agency will take “a phased approach driven by scientific data,” even while the FDA maintains its commitment “to first protect the health and well-being of not only our own highly skilled workforce but also the health of workers in the important industries we regulate.”

What’s the Appropriate Model?

During a webinar entitled “COVID-19 and Beyond: Development and Implementation of Recovery Action Plans for Medical Products Manufacturers” — presented May 19 by the Food and Drug Law Institute — Robert A. Rhoades, a managing partner with the health care consulting firm Validant, said that as manufacturing plants and operations come back online following the COVID-19 shutdown, FDA investigators will begin to return to the facilities.

However, he said, “it may be under a different circumstance,” given the importance of protecting the health of facility employees and agency investigators and the need for continued social distancing. “Those are real problems,” he said.

Joseph Jimenez, a managing director with Arches Consulting L.L.C., reported that many companies are beginning to consider what a virtual FDA inspection would look like and what the appropriate model for a virtual inspection should be. “We’re talking about something more than the straightforward document review,” he said. “I’ve seen proposals involving cameras with a live feed serving as a video component of an inspection.”

‘A Reality in the Not-So-Distant Future’

“Virtual inspections will be a reality in the not-so-distant future,” predicted Daniel Barreto, the president and chief executive officer of PharmQ Global Consulting L.L.C. “There will be a period of learning for both the industry and the regulators.” Agency regulators will “catch up in time” to the lessons of remote and virtual operations that the regulated industry has learned during the COVID-19 shutdown, he said.

Some people underestimate the feasibility of virtual inspections because investigators would not be present, Barreto said. However, he noted, about 95 percent of what most FDA investigators do is document review.

In fact, virtual inspections “could actually become a very powerful tool for the regulators,” Barreto said. A virtual inspection would give the investigators more time to design the type of approach that they are going to take to an inspection and to design the types of requests they are going to make, he said. This pre-inspection planning should help investigators put a facility’s condition and the requests that they make during the inspection “into the right perspective.”

For now, he suggested, FDA-regulated companies need to start planning how they would handle virtual inspections.

Possible Advantages, Dangers for Industry

Cathy L. Burgess, a partner in the Washington, D.C., office of Alston & Bird L.L.P., said that she suspected that most companies would be happy to provide a video and photographs as part of a virtual inspection if they thought that, for example, they could get a premarket inspection accomplished through record review and then have the FDA agree to conduct a virtual follow-up inspection that included video and photographs.

However, one possible obstacle may be a reluctance on the agency’s part to accept such evidence as a valid substitute for what FDA investigators could observe on-site. “The investigators want to see what’s going on in real time,” Burgess said.

The only reason why investigators want to take photographs, she said, is to memorialize something that they actually observed. In the past, investigators have requested video footage to review as part of an inspection. Companies can offer those things, Burgess said, but she would be reluctant to have a client offer all the video that exists concerning a particular operation or system.

“Eventually,” she said, “especially if this pandemic public health emergency goes on for a long, extended period of time or we have a resurgence of the virus, we’re going to have to have [virtual inspections] as an option.”

Possible Framework, Controls

A manufacturer would resist participating in a virtual inspection if the idea was to turn over every video or photo that it had, Jimenez suggested. However, if a company was trying to demonstrate the effectiveness of a certain manufacturing practice — for example, the validity of an airflow study — a company might create a video record of the practice and agree to provide it to the agency.

Companies would agree to virtual inspections “with that kind of framework and with those kinds of controls,” he said.

Access to Electronic Records, Systems

Another issue that could arise during a virtual inspection could be whether to provide an FDA investigator access to electronic records and computer systems in lieu of providing paper records — and what types of controls would be needed to manage such a request.

During a typical inspection, Burgess noted, an inspector might request to see the audit trails of a manufacturing system, and the investigator might sit down with a company analyst to review data. It would be “certainly possible” to have a remote version of that process, using a screen sharing function such as Webex, she said, so that the investigator could have a view of what’s going on at the site and could ask the facility staff to open certain records. “I think that would be appropriate,” she said.

By contrast, Burgess said, it would not be advisable to provide a system password to the investigator and let him or her “have free rein” to explore a company’s electronic systems and records. “You can’t remove the personal element or the need for FDA to make requests,” she said.

An organization needs to understand what the FDA is looking for, she stressed. “I would be hesitant to advise a client to just open up all of their electronic records and say, ‘Here’s everything. Find what you need,’” she said. “I don’t think that’s very helpful for the investigators either.”

Barreto agreed, saying that it was important to make a distinction between giving access to electronic records and giving access to electronic systems. It would be beyond the scope of an inspection merely to say, “Here’s the password. Do whatever you want,” he suggested. “That wouldn’t be any form of inspection,” he said. “That would be the same as sending hundreds of documents to an inspector and saying, ‘Here, take your pick.’ It just doesn’t work that way.”

During an inspection, he noted, the inspector needs to ask what he or she wants to see, and then the company provides it. “It’s a give-and-take,” Barreto said, “but it’s not an open-door policy.” It’s not that a company doesn’t want to be transparent and open, he suggested. “Every inspection has a beginning and end,” he said. “There have to be certain controls.”

Burgess noted that there can be situations where an investigator does not really know what he or she wants to see, or where the investigator knows what he or she wants to see but the company resists because the request would call for the production of “thousands and thousands of pages or records that have nothing to do with the issue that the investigator has in mind.”

Duplicating an On-site Inspection

The goal, Jimenez suggested, should be to duplicate in a virtual inspection what would happen if the inspection were on-site. On-site, he said, an investigator would typically ask for the subject-matter expert for a particular system to sit down, open up the system, and walk the investigator through it.

If that can process can be replicated through a virtual platform, “that’s probably the best model.” Jimenez said. “The investigator could say, ‘Stop, click here, open that,’ as the investigator would during an in-person inspection. If you approach a virtual inspection from that perspective, you can avoid some of the issues that we’ve identified.”