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FDA Exploring Use Of Video – 'Live Or Recorded' – To Support Virtual Inspections During Pandemic

The agency using video during inspection of a device firm could prove dicey given industry's general aversion to investigators taking photographs

by Shawn M. Schmitt

The US FDA is assessing via a pilot program whether the use of video is helpful when investigators perform remote facility inspections. Meanwhile, the agency's device center is "working on alternative approaches for assessing a firm's quality management system," an FDA official says.

For several months the US Food and Drug Administration has been exploring new ways to ensure manufacturer compliance during the COVID-19 pandemic. To that end, the agency is assessing via a pilot program whether the use of video is helpful in supporting virtual facility inspections.

"One of the things you always hear is, you never let a good crisis go to waste. And I think this opportunity is really helping us think about how we use our finite resources to the best public-health impact, to be good stewards of the resources we have and to really think through how we get the best public health outcomes," Elizabeth Miller, assistant commissioner of medical products & tobacco operations within the FDA's Office of Regulatory Affairs (ORA), said on 17 November at FDAnews' 15th Annual Inspections Summit.

That's why the agency is "studying how we might incorporate new technologies and tools to support our inspections, including exploring a pilot to assess the use of live or recorded video," she said. "We welcome the opportunity to work with regulated industry to understand and to discuss how this may affect [the FDA's] future procedures."

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> *"Our medical device program is working on alternative approaches for assessing a firm's quality management system." – Elizabeth Miller*

The FDA using video during the inspection of a device company could prove dicey given industry's longtime general aversion to investigators taking photographs. (Also see "*Photos Snapped During FDA Device Inspections: Fair Game Or Agency Overreach?*" - Medtech Insight, 9 Feb, 2016.)

But an agency spokesperson told *Medtech Insight* on 16 November that so far the video pilot has only been used for inspections related to human and animal foods. When it comes to medical devices, the spokesperson said, "the FDA is exploring many options for assessing firms during the pandemic and for the future. This could include pilots."

Medtech Insight first reported on 11 November that the agency has been quietly putting together a pilot program specifically for conducting virtual inspections of device manufacturers. (*See sidebar story.*)

Miller added some context in her comments at the Inspections Summit: "Our medical device program is working on alternative approaches for assessing a firm's quality management system. Using remote assessment is very much in line with the Quality System Inspection Technique," or QSIT.

QSIT is used by FDA investigators to make sure they look at the most important compliance issues and ask pertinent questions linked to four major quality system subsystems: management controls, corrective and preventive action (CAPA), design controls, and production and process controls.

The ORA – which conducts all of the agency's field activities – "is actively working with the center for devices in defining, identifying and prioritizing various medical device manufacturers for

FDA Quietly Plots Pilot Program For Virtual Inspections As Pandemic Rages On

By Shawn M. Schmitt

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The COVID-19 pandemic is nudging the US FDA to launch a voluntary pilot program that will allow agency investigators to conduct facility inspections virtually, King &

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contenders in these remote assessments," Miller said.

The FDA paused inspections in March at manufacturing facilities in the US and abroad. The agency *resumed domestic audits in July* in parts of the country where the pandemic allows – but those areas are few and far between.

Spalding's Steve Niedelman said on 11 November.

Read the full article here

The agency told *Medtech Insight* on 17 November that it has conducted only 35 on-site inspections of US device makers since the audits restarted on 20 July. That's roughly two per week – anemic for an agency that had *planned to perform 1,400 GMP inspections* of domestic device firms in fiscal year 2020, which ended on 30 September.

Miller wasn't able to say whether a virtual inspection will count as an official facility inspection in the eyes of the FDA.

"I think of inspections as sort of a spectrum of activities, and all of those things are used to inform our regulatory decision-making," she said. "Right now it's more important than ever that we are flexible, that we collaborate, that we come together to use all the information at our disposal so we can make the right decisions for the best public health outcomes, and that's what we're in the process of doing.

"While remote regulatory assessment or records requests will never completely substitute for an on-site GMP inspection, I think these activities are going to have outcomes that are going to help us make regulatory decisions."

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