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Here We Go Again: Omicron Forces FDA To Pause 'Certain Inspectional Activities'

by Shawn M. Schmitt

The COVID-19 pandemic's latest variant has pushed the US FDA to pump the brake once again on performing on-site surveillance inspections through at least 19 January. Meanwhile, an agency official says Remote Regulatory Assessments "are here to stay."

The COVID-19 Omicron variant has forced the US Food and Drug Administration to pump the brake once again on performing on-site surveillance inspections.

In a small blurb tucked away in a 4 January *news roundup* from the agency, the FDA explained that it decided on 29 December to put in place "temporary changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as the agency further adapts to the evolving COVID-19 pandemic and the spread of the Omicron variant."

While the FDA will continue to carry out domestic and foreign mission-critical inspections, the agency said it has "postponed certain inspectional activities" through at least 19 January. The FDA further said it's delaying the scheduling of foreign surveillance inspections that were slated to begin next month.

An FDA spokesperson told *Medtech Insight* on 5 January that "certain inspectional activities" "refers to non-mission-critical domestic and foreign surveillance inspections, investigations and sample collections that cannot be performed remotely or safely due to travel or social distancing concerns. We continue to balance our responsibility to provide public health protection with our responsibility to limit exposure to and spread of the virus."

Industry has seen this movie before. The FDA put a stop to routine *domestic* and *foreign* surveillance inspections in March 2020. Domestic surveillance inspections weren't resumed until July 2021, and the agency is still inspecting overseas companies only when it's deemed mission critical.

At a December Enforcement, Litigation and Compliance Conference presented by the Food and Drug Law Institute, FDA official Elizabeth Miller said "keeping the health and safety of our employees, as well as the employees in those facilities we regulate, is paramount" during the pandemic.

Miller is the assistant commissioner for medical products and tobacco operations for the FDA's Office of Regulatory Affairs. ORA is the lead office for all of the agency's field activities.

"One thing we've all learned through this public health emergency is to expect the unexpected, and that it's a dynamic and fluid situation. Not just with the current [Omicron] variant, but the Delta, we try to make adjustments," she explained.

RRAs 'Here To Stay'

One such adjustment is the FDA's move toward using a hybrid approach for inspections. Miller calls hybrid inspections "the new normal."

While on-site inspections are ideal, the agency has nevertheless "learned during COVID the inherent value of multiple tools that are available to us, and the need to develop new tools that can provide additional regulatory information," she said.

> *"Remote Regulatory Assessments are here to stay, even on the other side of the pandemic." – Elizabeth Miller*

Miller went on: "Hybrid inspections are anticipated to consist of a combination of tools and approaches that have emerged from the crisis, including assessments being conducted remotely, followed by on-site inspection at the facility. Much work is underway and being discussed in the international circles to evaluate the utility of the hybrid inspection in special controlled circumstances, and going forward expect more of the hybrid approach, asking for information in advance of the inspection."

One such tool is the FDA device center's Remote Regulatory Assessment (RRA) program, which is voluntary for industry. An RRA is used to help the FDA ascertain a manufacturer's general compliance with agency rules and expectations via records requests and video interactions. RRAs are not considered by the FDA to be official surveillance inspections. (Also see "*To RRA, Or Not To RRA? BD Talks Decision-Making Around FDA Requests For Remote Regulatory Assessments*" - Medtech Insight, 10 Jun, 2021.)

“Suffice it to say that Remote Regulatory Assessments are here to stay, even on the other side of the pandemic,” Miller said, adding that “the device program will continue the utilization of RRAs in the first quarters of FY ’22 to assist with the assessment of foreign firms.”

In a November report, the FDA said its new Inspectional Affairs Council, which was stood up last July, will develop RRA policy for all commodities the agency oversees. (Also see "*FDA’s New Inspections Council Whipping Up Policy Around Remote Regulatory Assessments*" - Medtech Insight, 24 Nov, 2021.)

Only Quarter Of Planned Device Surveillance Inspections Carried Out In FY ’21

The news that the FDA has again paused routine surveillance inspections comes a little more than a month after the agency trumpeted that it had performed more inspections in fiscal 2021 than it had planned.

The FDA said under a so-called “base-case scenario” that it would likely conduct only 851 of the 3,229 domestic surveillance inspections of makers of human and animal medical products that had originally been planned for fiscal year 2021, which ended on 30 September.

Speaking Of Medtech, Ep. 1 – Remote Inspections And Device Makers

By Steve Silverman and Shawn M. Schmitt

05 Oct 2021

In the inaugural episode of our new podcast series Speaking Of Medtech, former US FDA device center compliance chief Steve Silverman and *Medtech Insight* executive editor Shawn M. Schmitt discuss remote facility inspections and question whether they’re the wave of the future.

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But in a November update, the agency said it overperformed by carrying out 1,139 inspections, a 34% increase over its prediction.

However, when broken out by commodity, the FDA in FY ’21 conducted only roughly a quarter of the surveillance inspections it had planned for medical device establishments. According to figures given to *Medtech Insight* by the agency, it performed only 524 of 2,002 planned device inspections.

By comparison, the FDA conducted 258 of 515 planned surveillance inspections of drug makers in fiscal 2021, or about 50%.