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When Will FDA Inspections Resume? Agency Looks To CDC, White House For Guidance

FDA commissioner Hahn reminds manufacturers that "product safety and quality" should be paramount

by Shawn M. Schmitt

The US FDA is collaborating with the Centers for Disease Control and Prevention to determine the best way for agency investigators to perform on-site inspections again, using the White House's "Guidelines for Opening Up America Again" for guidance. Routine surveillance audits were paused in the US and abroad back in March.

With its surveillance inspections paused because of the COVID-19 pandemic, the US Food and Drug Administration is looking to the Centers for Disease Control and Prevention (CDC) and the White House for guidance in deciding the best way for investigators to perform on-site audits again.

The FDA back in March put the kibosh on conducting routine quality systems inspections at manufacturing facilities in the US and abroad. The agency had stopped inspections of Chinese plants in February.

For-cause inspection assignments, meanwhile, are still being carried out if they're deemed "mission critical" by the agency. But those types of audits aren't as common.

"The FDA is collaborating with the 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 'Guidelines for Opening Up America Again,'" FDA commissioner Stephen Hahn said in an *11 May statement*.

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The guidelines are meant to steer state and regional officials as they begin to reopen their economies.

The plan is made up of three phases. When a state or region has shown a downward trajectory in the number of documented coronavirus cases within a 14-day period – or a similar downward trajectory of positive COVID-19 tests among their population being tested within a 14-day period – they can move forward, step by step, into new phases of reopening specified businesses. (Also see "*Plan To 'Reopen' America Gradually Allows Return Of Elective Orthopedic, Colon, Eye Surgeries*" - Medtech Insight, 21 Apr, 2020.)

> ***"The FDA's regulatory oversight of crucial industry sectors is vital to the long-term health of America, but product safety and quality are ultimately the establishment's responsibility." – Stephen Hahn***

"We expect this to be a phased approach driven by scientific data," Hahn said of resuming routine inspections. "Our priority and commitment are to first protect the health and well-being of not only our own highly skilled workforce and state contract inspectors, but also the health of workers in the important industries we regulate."

While the White House guidelines will help inform the FDA's decision on when to send investigators back into the field within the US, it's not exactly clear what the agency's plan is for determining when it can once again conduct routine audits in foreign countries.

Hahn only said the agency will "continue to closely monitor the global situation and remain in contact with our domestic and foreign regulatory counterparts to inform our assessment of the feasibility of a return to routine on-site surveillance inspections as conditions improve."

He once again pointed out that the FDA has other "tools" it can use to determine a company's regulatory compliance, including import alerts, increased import sampling and screening, records-requests, and company compliance histories with regulators in other countries. (*See sidebar story for expert advice on surviving an FDA "desk audit."*)

A former FDA investigations branch director told *Medtech Insight* in March that she's concerned about the agency's pause on inspections, *noting that manufacturers can become lackadaisical* if they know they won't be seeing an agency investigator at their facility anytime soon.

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But Hahn doesn't seem to be worried about that.

"The FDA is confident in our ability to maintain oversight during this pandemic by leveraging all available authorities, alternative tools, and scientific methods to ensure the integrity and availability of safe and quality products," he said.

Nevertheless, Hahn gave manufacturers a veiled warning: "Safety and quality must be part of the daily routine at any regulated facility for their products to be high quality and reliably suitable for the US consumer. ...The FDA's regulatory oversight of crucial industry sectors is vital to the long-term health of America, but product safety and quality are ultimately the establishment's responsibility."

Compliance Corner: How To Survive An FDA 'Desk Audit' During The COVID-19 Crisis

By Shawn M. Schmitt

15 Apr 2020

A former US FDA investigations branch director explains how a paper-based "desk audit" would be performed by the agency in lieu of an on-site quality systems inspection. Last month the FDA hit the pause button on in-person inspections as the coronavirus pandemic rolls on.

Read the full article here

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