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On-Site Inspections Of US Device Makers Plummet 93% As FDA Scrambles For Virtual Solutions

US Regulatory Roundup, November 2020

by Shawn M. Schmitt

A sharp decline in the number of in-person facility inspections has forced the FDA to consider creative techniques for remotely evaluating manufacturer compliance during the COVID-19 pandemic. This and other stories topped our list of most-read *Medtech Insight* articles in November.

FDA Tests The Waters On Virtual Inspections

The number of on-site inspections of medical device facilities performed by the US Food and Drug Administration between mid-July and mid-November fell by an eye-popping 93% from the same time frame last year. That's forced the agency to consider creative techniques, including records requests and the use of video, for remotely evaluating manufacturer compliance during the COVID-19 pandemic.

The FDA told *Medtech Insight* it conducted a mere 35 domestic in-person inspections from 20 July – when the agency began inspecting again following a four-month break due to the coronavirus – through 17 November. By contrast, roughly 500 inspections were carried out from July through November 2019, agency data show.

In our *most-read story* from November, we exclusively reported on plans by the FDA's device center to set up a virtual inspections pilot program for makers of devices, given the dramatic decrease in on-site ones. The agency hasn't said much about the budding pilot since then, although FDA official Elizabeth Miller said during an industry conference last month that the agency's "medical device program is working on alternative approaches for assessing a firm's

quality management system."

Miller, who's assistant commissioner of medical products and tobacco operations within the FDA's Office of Regulatory Affairs, said the ORA "is actively working with the center for devices in defining, identifying and prioritizing various medical device manufacturers for contenders in these remote assessments." The ORA conducts all of the agency's field activities.

Meanwhile, the FDA has kicked off one pilot program and is forming another aimed at virtually gathering data from manufacturers. *The first involves the use of live or recorded video* to assess compliance, while *the other would allow investigators to remotely review records*.

The FDA told *Medtech Insight* that, as of 16 November, the video pilot has only been used for inspections related to human and animal foods, and Miller said on 17 November that the records request pilot is still in the planning stage. She pointed out that records can be "used as an indicator of a firm's compliance, and may allow us to focus and limit time needed on an on-site inspection, or in advance of an inspection to later occur."

QSR Harmonization Update

And in our *No. 3 story*, the FDA's Miller said the hotly anticipated draft of the agency's revised Quality System Regulation won't be ready for release until sometime next year. The FDA has been harmonizing its QSR with international quality systems standard ISO 13485 since 2018.

The agency has missed four internal deadlines for releasing a draft rule, the most recent of which was October, as we noted in our *No. 5 story* from November.

Biden Predictions

A trio of stories about President-elect Joe Biden also was of high interest to *Medtech Insight* readers last month.

In our *No. 4 story*, two industry attorneys laid out some pressing issues for the forthcoming Biden administration, including taking ownership of the pandemic, carrying out Medical Device User Fee Amendments (MDUFA V) negotiations, and tackling various digital and technology initiatives.

Further, Akin Gump partner Nathan Brown told *Medtech Insight* that the Department of Health and Human Services will likely align better with the FDA under a Biden administration when it comes to the oversight of laboratory developed tests. LDTs have been a point of contention between the HHS and the FDA since August, when the HHS hastily removed (via a *five-sentence policy statement*) the agency's oversight of the diagnostics.

"I wouldn't expect that Biden would continue [the policy on LDTs] in its exact form that HHS has

articulated," Brown said.

And in our *No. 7 story*, King & Spalding attorneys said Biden will likely rush to have the US Senate confirm new heads of the HHS and the FDA. One of those lawyers, Sheldon Bradshaw, predicted that "a new secretary of HHS and new FDA commissioner more likely will have a background in public health and academics, rather than someone who is coming out of industry."

Meanwhile, a member of the president-elect's COVID-19 task force said in our *No. 6 story* that the incoming administration will use the Defense Production Act on "day one" to ramp up the manufacture of personal protective equipment to fight the pandemic.

Other Top Stories

These articles rounded out our Top 10 list in November:

No. 2 story: Republicans and Democrats continue to point fingers at each other over COVID-19 relief legislation.

No. 8 story: The FDA updated its catalog of recognized regulatory science tools to review medical devices; the list includes the types of tools regulatory reviewers may use to determine if a sponsor's product meets requirements to go to market.

The 10 most popular US regulation and policy stories in November are listed in the table below.

Rank	Story
1	*FDA Quietly Plots Pilot Program For Virtual Inspections As Pandemic Rages On*
2	*House Speaker Pelosi, Treasury Secretary Mnuchin To Pick Up Negotiations Soon On COVID-19 Relief Bill*
3	*FDA Official Confirms 2021 For Release Of Draft QSR, Asks For 'Inclusive Comment Spectrum'*
4	*US Election 2020: What Does A Trump Or Biden Win Mean For FDA Regulations?*
5	*As Expected, FDA Misses Fourth Consecutive Deadline For Releasing Draft QSR*
6	*Biden Will Invoke Defense Production Act On 'Day One' To Ramp Up PPE Manufacture*
7	*Experts: Biden Will Rush To Fill HHS, FDA Posts; Georgia Senate Races May Decide ACA's Fate*
8	*US FDA Adds 14 New Regulatory Tools To Help It Review Medical Devices*
9	*FDA Cobbles Together Pilot For Remote Review Of Manufacturer Records*
10	*FDA Exploring Use Of Video – 'Live Or Recorded' – To Support Virtual Inspections During Pandemic*