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US FDA Explains How It Is Embracing Remote Assessments Post-Pandemic

by Bowman Cox

Agency provides new details on plans for various remote methods of assessing manufacturing establishments that became popular when investigators were prevented by COVID-19 pandemic travel restrictions from visiting sites in person.

The US Food and Drug Administration on 22 July said it will keep doing remote regulatory assessments of drug manufacturing plants, clinical investigator sites and other FDA-regulated establishments, even when the COVID-19 pandemic no longer prevents travel for site inspections – and provided some insight into why.

The experience the agency developed with various types of remote assessments during the public health emergency "has identified significant benefits of using RRAs to FDA, regulated industry and the public," the FDA explained in a notice scheduled for publication in the 25 July Federal Register.

Over the past two years, the agency has conducted more than 1,470 RRAs in the US and more than 600 abroad, according to an FDA statement attributed to the agency's commissioner, Robert Califf, and its associate commissioner for regulatory affairs, Judith McMeekin.

"RRAs are effective in getting essential information to regulators, enabling the FDA to intervene when needed and use agency resources more efficiently to do so," they said.

The agency described its plans for RRAs in a draft question-and-answer *guidance document*. It will consider comments filed within 60 days at regulations.gov in Docket No. FDA-2022-D-0810 when crafting the guidance's final version.

It's an approach that agency officials have been hinting at in recent months. (Also see "*How The*

US FDA's Inspectional Approach Is Shifting For The Post-Pandemic Era" - Pink Sheet, 14 Nov, 2021.)

The document provides basic information about the different types of RRAs the agency might conduct and what the regulated community should expect.

Mandatory Versus Voluntary

Participation in some RRAs is mandatory, but while participation in others is voluntary, it would be well advised, the agency suggests.

In the mandatory category are remote records requests made to drug manufacturing establishments under section 704(a)(4) of the Food, Drug & Cosmetic Act as well as requests to food importers for Foreign Supplier Verification Program records under section 805(d) of the FD&C Act. (Also see "*US FDA Assesses Over 500 Biopharma Plants Remotely Via Records Review; Refines Process*" - Pink Sheet, 17 Sep, 2020.)

Requests for interactive evaluations involving, for example, livestreaming video, teleconferences or screen sharing are strictly voluntary. The agency has previously issued guidance specific to remote interactive evaluations. (Also see "*Remote Site Visits Will Help US FDA Keep Reviews On Track During Remainder Of Pandemic*" - Pink Sheet, 14 Apr, 2021.)

Declining a mandatory assessment could lead to import refusal, while failing to volunteer could delay approvals or trigger inspections.

It is possible to add voluntary elements to a mandatory evaluation. For example, the agency said it could ask a firm for video streaming related to a records request.

The FDA has used RRAs to verify corrective actions taken in response to inspections, gain compliance insight and learn about deficient practices. It has relied on the insights obtained remotely for regulatory actions and inspection planning. In cases, it has used remote methods to support authorization or approval of FDA-regulated products during the pandemic.

Evaluations Versus Inspections

The FDA reaffirmed its position that RRAs are not inspections, which under the FD&C Act must involve physically entering facilities.

The agency gave examples of when it might deem an RRA appropriate, such as when travel limitations prevent inspections, or to prepare for a planned inspection, follow up on a consumer complaint or help verify whether an establishment has completed a corrective action.

The FDA said it will not simultaneously inspect and remotely assess an establishment. However,

it may participate a state or foreign regulatory partner's inspection through remote livestreaming, an approach the FDA and other regulatory authorities are jointly piloting. (Also see "*ICMRA's Pilot On Hybrid Inspections And CMC Changes Seeks Participants*" - Pink Sheet, 28 Jun, 2022.)

The FDA outlined examples of how remote assessments could benefit the agency, industry and the public:

- Remote evaluations could prompt corrective actions that better prepare facilities for their next inspection.
- Remote records requests could enable quicker inspections, saving everyone involved time and money.
- Remotely verifying information in marketing submissions could mean quicker approvals.

Process Outlined

The draft guidance provides practical information like how the FDA would contact an establishment to request or initiate an RRA, and notes that the agency only uses Form FDA 4003 for 704(a)(4) remote records requests.

Facilities that agree to host live streaming videos should be ready to host them properly, which means having Internet connectivity throughout the plant as well as appropriate security and privacy controls.

The draft guidance goes on to explain what types of records the FDA might request during an inspection, how it might use them, how quickly it would expect to get them and how they should be provided.

The End Game

How would an establishment know when the FDA has completed a remote regulatory assessment? The agency might schedule a meeting with site management to go over it or it might present a list of observations (similar to but different that the Form 483 observations delivered at the end of FDA inspections).

Industry has complained during the pandemic that that sometimes the agency does not say when it completes records reviews.

The agency asks for responses within 15 days of RRA completion, as it does for Form 483 responses.

RRAs ordinarily will culminate in a narrative report with supporting documents.

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The FDA said it will provide written copies of the reports' narrative sections to the establishment once it has determined that the RRA is closed per *21 CFR 20.64(d)(3)* – and make redacted versions of RRA reports available for public disclosure upon request.