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US FDA's Woodcock Outlines Plans For Quicker Inspection Workflow Platform, Expected Next Year

by Bowman Cox

Inspection ordering and case management software launched with food program revamp will bring real time coordination between the US FDA's inspectorate and all its centers, enabling quicker, surer deployment and better development of cases against sites found to have poor manufacturing practices.

The US Food and Drug Administration is working to establish a new platform for ordering inspections by fiscal year 2024, with back-end improvements in enforcement and case management efficiencies to follow, the agency's principal deputy commissioner Janet Woodcock said 2 March.

The agencywide inspection workflow solution will replace a patchwork of processes that failed to prevent last year's infant formula crisis. (Also see "*Reorganization Of US FDA's Office Of Regulatory Affairs Will Deliver More Preemptive Inspectorate*" - Pink Sheet, 2 Feb, 2023.)

Woodcock told an Alliance for a Stronger FDA webinar that Theresa Mullin, associate director for strategic initiatives at the agency's Center for Drug Evaluation and Research, and Carol Cave, deputy associate commissioner for regulatory affairs, are running a workstream on improving the inspection process. It's one of an implementation and change management group's four workstreams for the food center's reorganization, but one that will affect all the agency's centers.

"For almost two years now, FDA has been working on getting the inspection process across the agency onto a workflow management platform," Woodcock said.

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This way, staff would not have to rely on email, SharePoint or Excel spreadsheets to request inspections or obtain inspection results, she explained. “In other words, so everyone is on the same page.”

The agency is piloting the platform “using inspection protocols that have structured data elements,” including in the food area.

CDER and ORA have been working to develop and pilot the inspection protocols since 2014. (Also see "*FDA Aims for State of Quality with New Inspection Protocol Project*" - Pink Sheet, 29 Apr, 2015.)

In recent years, the agency has added inspection protocols and taken other steps toward data modernization. (Also see "*US FDA Seeks Funding To Modernize Inspection-Related Technology Systems*" - Pink Sheet, 19 Apr, 2022.) (Also see "*FDA Launches Protocol For Inspections Of Sterile Drug Manufacturing Facilities*" - Pink Sheet, 11 Nov, 2018.)

Requesting Inspections More Transparently

Mullin and Cave are focusing initially on improving the process of requesting inspections.

The way it works now, the centers send prioritized lists to the field using various methods such as spreadsheets and emails. “Then the field has its own work planning process that they do that is not transparent to the centers, or even completely to ORA, and it’s highly manual in its execution,” Woodcock said.

CDER has long used a site-selection model to set its surveillance inspection priorities. (Also see "*CDER Added Some Flexibility in 2007 to Inspection Site Risk Ranking Model*" - Pink Sheet, 1 Nov, 2007.)

CDER’s Office of Pharmaceutical Quality outlined the policies and procedures for its site-selection model as of September 2018 in an internal manual at *MAPP 5014.1*.

“We would like to get a totally transparent, optimized process where everybody’s working together, they do it once, but it’s also dynamic, and everybody can see the results. And then that will be put onto the workflow management platform that we have.”

Building Stronger Cases

Meanwhile, Woodcock and Cave are beginning to work on the project’s second step, which focuses on case workup. “Once a problem is found in a facility, what we would like to see is forming a multidisciplinary team immediately.”

Whatever subject matter experts or lawyers are needed would be available right away so the

investigator can efficiently collect the right evidence to work up a case if there's going to be an enforcement action, she said.

"Once that process is worked out, it'll be put on the workflow management platform, which we hope next year that we will be standing that whole thing up."

Where The Funding Will Come From

Woodcock touched on the inspection-related IT issues in her reply to a question about the role of underfunding in causing the food program's problems and the budget implications of the fixes. Whether it resulted from money problems or design problems, "it's probably going to need money to fix regardless of how we got there."

She noted as well that the agency is moving a lot of the IT development up from ORA to the Office of Digital Transformation, led by FDA chief information officer Vid Desai, who reports to Commissioner Robert Califf, and to the Enterprise Transformation Operation team, which is based in the commissioner's office.

The fiscal year 2024 budget request that the Biden administration will send over to Congress on 9 March won't reflect the reorganization and any associated costs, Woodcock said. Instead, the FDA will seek any funding needed through a reprogramming request that will accompany the reorganization package.

Why Matrix Beats Line Management

She parried concerns that the revamped food center will still lack line management authority over inspectors by asserting that the matrixed approach works better, with the centers focusing on their subject matter expertise while ORA focuses on its inspection expertise.

"We're going to make ORA a leaner organization that is focused on its core capabilities, which is inspections, the laboratories, as well as sampling, the border, criminal investigations and other investigations, those sorts of things that are uniquely ORA disciplines and capabilities."

The centers will set the strategy in terms of what concerns ORA will address, what it will sample, what sites it will target and how many inspections it will conduct.

Why Better Workflow Is Key

The agency's centers will benefit far more from the visibility into ORA that the planned agencywide IT backbone for ordering inspections and managing cases will deliver than they could by managing inspectors directly without the IT workflow process improvements, she asserted.

“Right now, the inspections are directed by the center,” she said. “However, due to the problems in the work planning process, nobody really knows what’s going to get done. All right. And so, we’re going to try and fix those things.”

The solution has two parts, she said. “Part of it will be making clear who has the decision capability, and part of it will be designing the processes and workflow systems that enable these things to actually happen.”

Speaking From Experience

Asked about the pushback she’s been getting for not putting ORA’s food inspectors under the deputy commissioner slot planned for the food program, she said, “that’s because those people … wouldn’t have to run that program.”

“I think the people who are calling for this really haven’t operated a large organization at a very detailed level, which I have done numerous times,” Woodcock said. “I just really feel like we shouldn’t be doing an old-style organization. We should be doing a modern matrixed organization so we get the most bang for the buck for the taxpayer.”