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# FDA Says It's Approving Change Notices 3 Weeks Faster For Firms In CMMI Maturity Model Program; 40+ Inspections Waived

by Shawn M. Schmitt

The US agency is approving 30-day change notices at a breakneck pace for device-makers enrolled in an ongoing program that measures manufacturing maturity and quality using an industry-modified version of the Capability Maturity Model Integration (CMMI) framework. FDA also says it has waived 40 routine and four pre-approval inspections as part of the program – a help not only to device firms, but to the agency as it considers where best to use its scarce inspectional resources.

US FDA is approving 30-day change notices at a breakneck pace for device-makers enrolled in an agency program that measures manufacturing maturity and quality.

That's according to Cisco Vicenty, a program manager in the Office of Compliance within FDA's Center for Devices and Radiological Health (CDRH). He says the agency is approving the notices within a brisk three-day window, on average.

Such notices – filed by firms when they make noteworthy changes to manufacturing or other processes – are typically approved in about 24 days.

Having change notices quickly reviewed is one of the perks for firms that play in the agency's Case for Quality Voluntary Improvement Program. (Also see "*Chasing Quality Isn't Easy. But An FDA Pilot Aims To Boost Quality By Appraising The Capability Of Manufacturing Sites*" - Medtech Insight, 7 May, 2018.)

*Known until recently* as the Voluntary Medical Device Manufacturing and Product Quality Pilot Program, CFQ VIP aims to elevate product, manufacturing and process quality at device firms by

appraising the companies against an industry-modified version of the *Capability Maturity Model Integration* (CMMI) framework.

Aside from a fast turnaround on change notices, companies in the program see other benefits from the agency, including streamlined and accelerated options for site transfer changes and pre-market submissions.

At a Feb. 25 Case for Quality forum, Vicenty said more than 45 change notices have been submitted to FDA since CFQ VIP began as a yearlong pilot program in January 2018. (CFQ VIP is now a full-fledged, ongoing agency program.)

Under CFQ VIP, FDA gives itself five days to review a manufacturer's notice – a goal it's more than meeting.

> ***One device-maker enrolled in CFQ VIP made more than $15m in extra sales over the 21 additional days it would've spent waiting for FDA to approve its notice.***

"The average time now is ... probably 2.8 days to approval for change notices" for firms in CFQ VIP, said Vicenty, who is also a leader for the popular *Case for Quality*. "One of the more interesting things we're seeing ... is that some notices are being approved even more quickly than that."

In one instance, a change notice was approved by FDA reviewers in 13 hours, while another took less than 16 hours.

"And now we're always getting a nice email when someone has gotten a modification sent out and approved in even less time than that. It's almost like, a little competition now internally" to see who can approve a change notice the fastest, he quipped. Nevertheless, Vicenty insists that reviewers are "doing things the right way."

Having the ability to implement changes three weeks quicker has had a positive impact on manufacturers in the CFQ VIP program, Vicenty said. He noted that one firm saved $286,000 related to one change, while another company made more than $15m in extra sales over the 21 additional days it would've spent waiting for FDA to approve its notice.

And, at another device firm, a quick change allowed it to increase its production capacity by 11%. "The 21 extra production days resulted in 882 additional high-risk patients receiving products and treatment. That's a big deal," Vicenty said.

## FDA Waives 40 Routine Inspections

Firms enrolled in CFQ VIP also don't face regularly scheduled facility inspections, and pre-approval audits are waived.

Vicenty said FDA has waived 40 routine and four pre-approval inspections as of Feb. 25 – a help not only to device firms, but to the agency as it considers where best to use its scarce inspectional resources.

FDA, however, reserves the right to conduct an inspection if it is for-cause – something it has done three times at CFQ VIP-enrolled firms.

"We had some for-cause inspections, but they needed to happen. For-causes are still part of what is on the table for us to do," Vicenty said, adding that the inspections served as a positive "validation check."

"The results [from the three for-cause inspections] were no observations for the companies as they've gone through the process. So, it's been a very positive reflection" for those manufacturers, he said.

*From the editors of The Gray Sheet*