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FDA Mulls Variant CMMI Maturity Model Program For 'Struggling' Device Companies

by Shawn M. Schmitt

Device-makers that are shut out of the US agency's Case for Quality Voluntary Improvement Program (CFQ VIP) because of poor compliance histories may soon be able to join an alternative initiative that would use an industry-tailored version of the Capability Maturity Model Integration (CMMI) framework to assess manufacturing maturity and quality.

Device-makers with less-than-stellar compliance histories may soon be able to join a variation of a program offered by the US Food and Drug Administration that assesses a company's manufacturing maturity and quality.

The Case for Quality Voluntary Improvement Program (CFQ VIP) – run jointly by the agency and the Medical Device Innovation Consortium (MDIC) – 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.

To date, more than 20 firms have enrolled in CFQ VIP and roughly 50 manufacturing sites have been appraised under the 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.)

> ***If struggling firms "are part of the appraisal program and we have a good plan for improvement and oversight, we might be a lot softer in the more traditional enforcement actions we take." – Jeff***

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Shuren

Only manufacturers with clean compliance records are accepted into CFQ VIP. Companies that play in the program must have "No Action Indicated" (NAI) or "Voluntary Action Indicated" (VAI) results from FDA inspections conducted over the past five years. Favorable results from Medical Device Single Audit Program (MDSAP) audits are also accepted.

Because of that requirement, there are many firms that aren't eligible to join CFQ VIP – even if they want to improve their processes by using the industry-modified CMMI approach.

That's why the FDA is collaborating with the MDIC and Pittsburgh, PA-based CMMI Institute "to develop a variation of the VIP program for struggling sites," says Cisco Vicenty, the *Case for Quality* program manager in the FDA's Office of Product Evaluation and Quality (*OPEQ*), within the Center for Devices and Radiological Health (CDRH).

"We have always known that there's the potential for applying this [CMMI] methodology and approach" to device-makers that don't make the cut for CFQ VIP, Vicenty said during a 27 August *webinar* update on the program. "There's work ongoing that we are engaged in that will help really start and create a variant of this approach for those sites that are struggling."

CDRH director Jeff Shuren confirmed on 5 May at the MDIC's Annual Public Forum that the agency is considering an alternative CMMI program.

It's "one of the things we're thinking about for those companies that, they're really not doing so well [and] they kind of need to get to a good baseline before they truly can get on that road to continuous quality improvement," Shuren said.

"There may be the opportunity that, if they are part of the appraisal program and we have a good plan for improvement and oversight, we might be a lot softer in the more traditional enforcement actions we

Catching Fire: FDA's Manufacturing Maturity Program For Devices Spreading Internationally – And To Drug Facilities

By Shawn M. Schmitt

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The US agency's Case for Quality Voluntary Improvement Program – used to measure a device-maker's manufacturing maturity and quality – has surprisingly been used to assess some pharmaceutical facilities. Meanwhile, regulators from other countries have been

take," he added. For example, "we would be holding off where we would otherwise issue a warning letter."

Manufacturers enrolled in CFQ VIP receive a bevy of benefits from the FDA, including streamlined and accelerated options for 30-day notices, site-transfer changes and premarket submissions. Program enrollees also don't face regularly scheduled facility inspections, and pre-approval audits are waived.

reaching out informally to the FDA to learn more about CFQ VIP.

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