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FDA's Case For Quality Head Explains The Agency's 2020 Maturity Model Pilot For Naughty Manufacturers

by Shawn M. Schmitt

Cisco Vicenty tells how the US agency will structure its pilot program for device-makers with less-than-stellar compliance histories that want to use the CMMI maturity model framework to improve the quality and maturity of their manufacturing organizations – and clean up their compliance problems along the way. The FDA – which is partnering with the Medical Device Innovation Consortium (MDIC) and Pittsburgh's CMMI Institute on the voluntary pilot – will offer the opportunity to 10 firms "that have had a negative inspection outcome, a warning letter, or possibly other regulatory action," Vicenty explains to *Medtech Insight*. The pilot launches next year.

The US Food and Drug Administration will be looking soon for 10 manufacturers with problematic compliance histories to volunteer to play in a pilot program to improve the quality and maturity of their manufacturing organizations – and clean up their compliance issues along the way.

Launching in 2020, the voluntary pilot – colloquially known as the Noncompliant Site Voluntary Improvement Program (NSC VIP) – will be modeled on the agency's burgeoning *Case for Quality* Voluntary Improvement Program (CFQ VIP).

CFQ VIP is run jointly by the agency and the Medical Device Innovation Consortium (MDIC). It 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. (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.)

The agency announced on 21 October that it awarded the MDIC S2.8m to help develop NCS VIP, and for other quality-related activities. (Also see "*FDA Awards MDIC $2.8M To Extend Maturity Model Program To Noncompliant Firms, Launch Cybersecurity 'Boot Camp,' And More*" - Medtech Insight, 23 Oct, 2019.)

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"Through the CFQ VIP pilot, FDA has seen significant systemic improvements at participating manufacturers," said 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).

"The same principles of the CMMI quality maturity appraisal apply to those organizations with a quality system that is not effectively compliant," he told *Medtech Insight* in an email interview.

Only manufacturers with clean compliance records can take part in CFQ VIP. Device-makers enrolled 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 on NCS VIP.

"The original CFQ VIP pilot was geared toward compliant manufacturers in the medical device space and was designed to improve the integration of the quality system," Vicenty said. Meanwhile, "the NCS VIP pilot is envisioned to be for manufacturers that have existing compliance issues. [The pilot] will be open to manufacturers that have had a negative inspection outcome, a warning letter, or possibly other regulatory action."

The pilot, however, will not be for start-up firms or new manufacturers that "want to establish the initial compliance of their quality system," he said.

Once developed, "the NCS VIP pilot will begin evaluation with 10 voluntary participants,"

Vicenty said. “After the pilot, if successful, the operating details will be incorporated into the CFQ VIP program as an additional offering for advancing quality and patient safety.”

A Different Approach

The CMMI appraisal process used under CFQ VIP – *reported* on *extensively* by *Medtech Insight* – will be modified for NCS VIP so it’s tailored to particular quality system issues.

“The customization will be specific to the manufacturing site,” Vicenty said. “This is very different than the current CFQ [VIP] approach, which has a specified set of practice areas that align with the modifications FDA was making.”

What’s In A Name?

The "NCS VIP" moniker may not be the pilot program's official title when it begins. After all, CFQ VIP was the CDRH Voluntary Medical Device Manufacturing and Product Quality Program before the FDA changed the name earlier this year. (Also see "*What's In A Name? FDA To Rechristen Its Popular CMMI Maturity Model Appraisal Program This Year*" - Medtech Insight, 24 Jan, 2019.)

An NCS VIP appraisal “may incorporate” quality metrics for particular products made by participating device-makers in an effort to “provide insight into [their] safety performance,” he added.

And there will be more of a “compliance check” under NCS VIP than what happens during a routine CFQ VIP appraisal.

“There will be more transparency with regards to the compliance issues and work-in-progress by” firms in NCS VIP, Vicenty said. “In order to ensure public safety while potential participants improve under this pilot, FDA may need more transparency and engagement.”

But he offered a caveat: “There is still a great deal of detail that needs to be developed” around NCS VIP – and things can change.

Closing Out Compliance Problems Faster

While the approach to the variant maturity model program will be similar to that of CFQ VIP, firms involved in NCS VIP will not see any special benefits from the FDA for taking part.

That's a departure from CFQ VIP, wherein enrollees are given streamlined and accelerated options for 30-day notices, site-transfer changes and premarket submissions. CFQ VIP firms also don’t face regularly scheduled facility inspections, and pre-approval audits are waived. (Also see "*Gifts For Industry: From Waived Inspections To Pre-Market Leeway, US FDA Woos Firms For Maturity Pilot*" - Medtech Insight, 25 May, 2017.)

Instead, “there will be modified approaches to engagement, especially as we are developing and piloting the effort,” Vicenty said, noting that firms in the pilot “may see a change in the way FDA engages throughout the resolution process, and the degree of effort in official responses to FDA.”

And he claims that NCS VIP will help manufacturers close out their compliance problems faster.

“Following the compliance resolution and results, the participant may transition [to CFQ VIP], which will then enable some of the modifications,” Vicenty said. But “these are just preliminary thoughts, as the pilot is being developed.

“There will be more details available as the process progresses.”