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

by Shawn M. Schmitt

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

A popular-with-industry approach for measuring a device-maker's manufacturing maturity and quality has surprisingly been used to assess some pharmaceutical facilities.

So says Cisco Vicenty, the *Case for Quality* program manager in the US Food and Drug Administration's Office of Product Evaluation and Quality (*OPEQ*), within the Center for Devices and Radiological Health (CDRH).

The agency – with help from the Medical Device Innovation Consortium (MDIC) – uses a device industry-modified *Capability Maturity Model Integration* (CMMI) framework for its burgeoning 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.)

To date, more than 20 firms have enrolled in CFQ VIP and nearly 50 manufacturing sites have been appraised under the program. (Also see "*Boston Scientific, Edwards Lifesciences, Baxter Used CMMI To Measure Their Manufacturing Capability. Here's What They Said About The Experience*" - Medtech Insight, 25 Jun, 2018.)

"One of the things that we have been seeing a little bit more of, which is quite interesting, is that participating [device companies are] enrolling other sites [in CFQ VIP] – sites that are not

medical device manufacturers," Vicenty said at a 20 June Case for Quality forum at MDIC headquarters in Arlington, VA.

> *"They're enrolling pure pharma sites [in CFQ VIP]. Now, what we are going to do with that down the road, I'm not sure, but it's happening." – Cisco Vicenty*

Some large manufacturers that play in CFQ VIP also have pharma plants under their corporate umbrella. Vicenty said those firms are using the device-centered CMMI framework at their drug facilities to help drive continuous improvement there, too.

"They're enrolling pure pharma sites" in CFQ VIP, he said. "Now, what we are going to do with that down the road, I'm not sure, but it's happening."

While there are different types of CMMI frameworks available to companies across an array of industries, Vicenty said it was ultimately the prerogative of those firms to use the device-centered approach at their pharma facilities.

"That's the way the companies wanted to apply it – it was their choice. So there wasn't a need to punt" to a different type of maturity model framework, he said. "They have contact points [at Pittsburgh, PA-based CMMI Institute] if they want to go further and try something different.

"But I think they saw enough benefit, that [the device framework] was the model they wanted to focus on and use."

Interest From International Regulators

Meanwhile, regulators from other countries have been reaching out informally to the FDA to learn more about CFQ VIP.

Vicenty said the FDA wants to have more serious discussions about the program with OUS regulators soon, after the agency has more complete data to share. (Although it was a pilot program for a few years, CFQ VIP was made a full-fledged program only recently, in January 2019.)

"We want to be able to get through enough with the participants to have data to bring back to the table, because when you're talking about [the global] community, you have to have something to

show for it to say, 'It's not just an idea. Here's the kind of results we're talking about. There's something here that we can leverage,'" he said.

CMMI appraiser George Zack said at the CFQ forum that regulators in other countries also need to have the will to put such a program in place.

> *"I do I think there's an opportunity" to bring CFQ VIP to the wider international community. – George Zack*

"For a program like this to be successful, you need a [CDRH director Jeff] Shuren and a Vicenty in that foreign regulatory body to be visionary to say, 'Hey, we're willing to provide regulatory modifications or benefits to get that started,'" said Zack, who is also principal and cofounder of Two Harbors Consulting.

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. (Also see "*Gifts For Industry: From Waived Inspections To Pre-Market Leeway, US FDA Woos Firms For Maturity Pilot*" - Medtech Insight, 25 May, 2017.)

"I do I think there's an opportunity" to bring the program to the wider international community, Zack said. "But there's just so much to consider, particularly with Brexit and the number of notified bodies [involved with the EU's new Medical Device Regulation (MDR)], and trying to find the right people in those organizations to get [a program] going there."

For its part, the CMMI Institute is eyeing working with regulators in other countries, says Kimberly Kaplan, CMMI's program operations manager.

Within the institute, "we're looking to meet soon to start the conversation about how we might do an approach like that," Kaplan said at the forum.

But there's no hurry, she added. "If we have to choose between doing it fast and doing it right, we want to do it right."