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Make America Manufacture Again? FDA Incentivizing 'Smart Manufacturing Solutions' To Shift Device-Making To US

by Shawn M. Schmitt

The FDA wants to "Bring MedTech Manufacturing Home" – and it's well on its way to fulfilling that goal with its burgeoning Case for Quality Voluntary Improvement Program for measuring manufacturing maturity and quality. But the agency – which has already received $6m from Congress for its America-centric initiative – is working on other programs that it hopes will spur medical device innovation and production in the US.

The Food and Drug Administration wants to spur medical device innovation and production in the US with its new "Bring MedTech Manufacturing Home" initiative – and the agency already has a leg up on that goal with its ongoing program that measures device-makers' manufacturing maturity and quality.

The FDA received $6m in funding in fiscal year 2019 for Bring MedTech Manufacturing Home, a program the agency says is needed to "shift more [device] production to the United States."

"Manufacturing innovation has stagnated in recent years as manufacturers have focused on meeting the basic requirements to ensure compliance with FDA regulations," the FDA claimed in a *March budget request*, wherein it asked for an additional $12m in FY 2020 for the America-centric initiative.

"To overcome this challenge, FDA will establish a more modern and nimble framework that will make it more efficient for device developers to implement smart manufacturing solutions and innovate manufacturing processes in ways that can allow devices to better meet the needs of patients and providers," the agency wrote.

That framework, the FDA says, includes a voluntary program for device firms to become certified for meeting specific manufacturing and product quality criteria.

"As part of this approach, the FDA would recognize third-party certifiers and offer regulatory incentives for those manufacturers who receive certification demonstrating their quality capability," Jeff Shuren, director of the FDA's Center for Devices and Radiological Health (CDRH), wrote in a *February statement*.

"These actions would increase manufacturing innovation, accelerate availability of high-quality devices to patients and foster a competitive marketplace around device quality similar to other industries, such as automotive and aerospace, that would advance device innovations, reduce manufacturing costs, and improve the quality and safety of medical devices," he added.

If Shuren's words ring familiar, that's because the agency has already been doing just that with its popular-with-industry *Case for Quality* Voluntary Improvement Program (CFQ VIP).

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 tried-and-true *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.)

Manufacturers that play in CFQ VIP receive a bevy of benefits from the agency, including streamlined and accelerated options for 30-day notices, site-transfer changes and premarket submissions. Program enrollees also won'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.)

> ***For many people, "Bring MedTech Manufacturing Home" may conjure thoughts of the "Make America Great Again" slogan – and that didn't happen by accident.***

Cisco Vicenty, the Case for Quality program manager within CDRH's new *Office of Product Evaluation and Quality* (*OPEQ*), confirmed that CFQ VIP falls under the banner of Bring MedTech Manufacturing Home.

"The Case for Quality VIP initiative is part of what's under that [Bring MedTech Manufacturing Home] umbrella for establishing a third-party mechanism – one that will allow us to use a lot of what we've already put into practice, and make that a sustained and operational operation and mode for future activities," Vicenty said during a *15 May webinar* updating stakeholders on the status of CFQ VIP.

"It allows us then to start working and partnering with other organizations to make sure that we are advancing a lot of what can be done within the manufacturing space as much as possible here domestically, and then where it spreads also internationally from there," he said. "But the focus is going to start" in the United States.

The FDA partnered with the Medical Device Innovation Consortium to stand up CFQ VIP, and the agency specifically called out the *MDIC* in its FY 2020 budget request as a group it will continue to partner with to bring other Bring MedTech Manufacturing Home activities to life.

Vicenty acknowledged that other manufacturing- and quality-related initiatives will fall under Bring MedTech Manufacturing Home, but he isn't certain yet what those will look like.

"It's a very broad umbrella," he said.

In an interview with *Medtech Insight*, MDIC program director Stephanie Christopher agreed with Vicenty's characterization of Bring MedTech Manufacturing Home.

"Bring MedTech Manufacturing Home isn't really so much a single initiative, as it's kind of this broad array of activity where FDA will continue to push the priorities they've had for some time, which is to encourage advanced manufacturing practices, encourage quality across medical device manufacturing, and all the activities that fall under that, including the Case for Quality initiative and Case for Quality VIP," Christopher said.

Know Your Audience

For many people, "Bring MedTech Manufacturing Home" may conjure thoughts of President Trump's "Make America Great Again" slogan – and that didn't happen by accident.

After all, the FDA has to play to its audience – in this case, Trump himself.

To secure funding, the "FDA has to pitch this to Congress and ultimately to the president, and so, the agency's kind of pitching it as, 'Hey, we're going to bring medtech manufacturing home,'" the MDIC's Christopher said.

"It's a shorthand for all of these initiatives to really drive high-quality, high-tech advanced manufacturing practices across the medical device industry."