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FDA Awards MDIC $2.8M To Extend Maturity Model Program To Noncompliant Firms, Launch Cybersecurity 'Boot Camp,' And More

by Shawn M. Schmitt

The US agency has awarded $2.8m to the Medical Device Innovation Consortium (MDIC) to develop a variant maturity model program for noncompliant device-makers, launch a "boot camp" on cybersecurity threat modeling for devices, and study advanced manufacturing practices used in other industries.

The US Food and Drug Administration has awarded $2.8m to the Medical Device Innovation Consortium (MDIC) to develop a variant maturity model program for noncompliant device-makers, and for other activities.

Medtech Insight reported last month on the FDA's interest in developing a modified version of its popular *Case for Quality* Voluntary Improvement Program (CFQ VIP) for manufacturers with poor compliance histories. (Also see "*FDA Mulls Variant CMMI Maturity Model Program For 'Struggling' Device Companies*" - Medtech Insight, 17 Sep, 2019.)

CFQ VIP – run jointly by the agency and the 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. (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 expansion of [the Case for Quality] will enable us to further collaborate with MDIC to enhance the success of CFQ VIP." – Jeff Shuren*

But only device-makers with clean compliance records can take part in CFQ VIP – and that's where the upcoming program for noncompliant manufacturers would come into play.

"The expansion of [the Case for Quality] will enable us to further collaborate with MDIC to enhance the success of CFQ VIP while promoting high-quality devices and increasing patient safety," Jeff Shuren, director of the FDA's Center for Devices and Radiological Health (CDRH), said in a 21 October release from the MDIC announcing the award.

Medtech Insight has been told by industry insiders familiar with CFQ VIP that the new program will be called the Noncompliant Site Voluntary Improvement Program (NCS VIP).

However, the "NCS VIP" moniker hasn't been confirmed by the FDA or the MDIC, and may not be the program's official title when it begins. After all, CFQ VIP was the CDRH Voluntary Medical Device Manufacturing and Product Quality Program before the agency 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.)

The MDIC's release says the VIP program for noncompliant firms "will apply the systemic improvement focus of the quality maturity appraisal used by the CFQ VIP, product safety metrics, and incorporate regulatory compliance perspective using the ISO 13485 standard."

ISO 13485:2016 from the International Organization for Standardization (ISO) is used by device firms to ensure quality systems compliance with regulators in a variety of countries, including Canada, Japan, Australia and the 28 member states of the EU. The FDA is currently working to harmonize its Quality System Regulation with the standard. (Also see "*QSR/ISO 13485 Harmonization Update: FDA Enforcement Discretion Likely When New Rule Stands Up; Draft Reg Coming By Year's End*" - Medtech Insight, 26 Sep, 2019.)

While the approach to the variant maturity model program will be similar to that of CFQ VIP, firms involved in the noncompliant version of the VIP program probably won't receive 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.

The $2.8m earmarked for the MDIC likely came from a pot of money given to the FDA by Congress for a so-called "Bring MedTech Manufacturing Home" initiative. (Also see "*Make America Manufacture Again? FDA Incentivizing 'Smart Manufacturing Solutions' To Shift Device-Making To US*" - Medtech Insight, 6 Jun, 2019.)

The agency received $6m in funding for fiscal year 2019 for Bring MedTech Manufacturing Home, which is the umbrella initiative for the FDA/MDIC Case for Quality program. In a *March budget request*, the FDA asked for an additional $12m in FY 2020 for the America-centric initiative.

Advanced Manufacturing And A Cybersecurity 'Boot Camp'

But the MDIC won't spend the entire $2.8m on developing a maturity model program for noncompliant device-makers. The group says it will also use the money to "study the adoption and use of advanced manufacturing practices" used in other industries to determine whether they can be adopted by the medtech industry.

And the MDIC will use the funds to launch a "boot camp" on cybersecurity threat modeling for devices.

"A systematic approach to threat modeling can enable manufacturers to effectively address system level risks, including but not limited to risks related to the supply chain, design, production and deployment," the MDIC said in its release. "As an integral part of managing medical device cybersecurity risk, integration of threat modeling provides a blueprint to strengthen security through the total product life cycle of medical devices."