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FDA's Popular CMMI Maturity Model Appraisal Program Soldiers On In Spite Of COVID-19

Virtual CMMI appraisals could be on the way

by [Shawn M. Schmitt](#)

The Case for Quality Voluntary Improvement Program, run jointly by the US FDA and the Medical Device Innovation Consortium, is leaning heavily on remote quarterly checkpoint meetings with participants in lieu of on-site appraisals. CFQ VIP aims to elevate product, manufacturing and process quality at device firms by assessing the companies against a modified version of the Capability Maturity Model Integration (CMMI) framework.

As the world continues to grapple with the coronavirus pandemic, a popular program that aims to assess the manufacturing maturity of medical device firms is soldiering on.

The [Case for Quality](#) Voluntary Improvement Program – or CFQ VIP – is run jointly by the US Food and Drug Administration 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 safety of everyone is the first priority of VIP, and FDA is providing the flexibility and support to ensure that. With that, VIP has postponed all in-person appraisals during this crisis," Kimberly Kaplan, program operations manager for Pittsburgh-based CMMI Institute, told *Medtech Insight* on 6 May.

CFQ VIP stakeholders are exploring ways to pilot test virtual CMMI appraisals.

In lieu of on-site assessments, CFQ VIP is leaning heavily on quarterly checkpoint meetings with participants to monitor their progress. The one- to two-hour remote meetings offer updates on how a firm is progressing on any issues pinpointed during a previous appraisal, among other discussion topics. A company's performance metrics are also submitted at that time.

"These activities have generally been conducted remotely and VIP is extending the continuation of these checkpoints during postponement to provide visibility into issues that may present themselves in light of the current operating state," Kaplan said.

In the meantime, stakeholders are exploring ways to pilot test virtual CMMI appraisals.

"This virtual pilot is being developed very deliberately to maintain quality and consistency in the appraisal approach and results," Kaplan said. "Criteria for this option is still under development."