MEDTECH INSIGHT
CITELINE COMMERCIAL

11 Jul 2019 | **News**

Thermo Fisher VP Wants More IVD Firms Involved In FDA's Manufacturing Maturity Program (Even Though His Company Isn't)

by Shawn M. Schmitt

Peter Shearstone, VP of global quality assurance and regulatory affairs at *in vitro* diagnostic test-maker Thermo Fisher Scientific, is dismayed that only two IVD manufacturers are playing in the US FDA's Case for Quality Voluntary Improvement Program to measure manufacturing maturity and quality – and his firm isn't one of them. "Part of my challenge is moving my company toward proactivity, and if [CFQ VIP] can help do that, then I'd be hypocritical if I didn't embrace it," he says.

In a textbook case of "do as I say, not as I do," a *Thermo Fisher Scientific Inc.* VP is urging more *in vitro* diagnostic manufacturers to participate in a US Food and Drug Administration program to measure manufacturing maturity and quality – despite his own company not taking part.

Peter Shearstone, VP of global quality assurance and regulatory affairs at IVD test-maker Thermo Fisher, bemoaned the anemic enrollment of *in vitro* diagnostic firms in the agency's *Case for Quality* Voluntary Improvement Program (CFQ VIP) at a 20 June Case for Quality forum in Arlington, VA.

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.)

Of the more than 20 companies that have enrolled in CFQ VIP over the past few years, only two of them were IVD firms. One is San Diego, CA-based *Illumina Inc.*; the other was not identified by

the Medical Device Innovation Consortium (MDIC), which partners with the FDA on CFQ VIP. ("Typically with the CFQ VIP, we don't disclose the sites involved in the pilot," MDIC program director Stephanie Christopher told *Medtech Insight* in an 11 July email.)

The IVD industry "has to absolutely get away from being a reactive business. I think we thrive on – maybe as human beings – the excitement of problem-solving and saving the day, but the reality of it is, we have to do a lot more proactive things to avoid the mistakes – the errors – from happening in the first place," Shearstone said.

He noted that one of the ways for IVD firms to be more proactive is to play in CFQ VIP.

"I look at ... CFQ VIP as a way to move the thinking toward proactivity and getting out of the routine of always going from crisis to crisis," Shearstone said.

Although he says CFQ VIP is "an interesting opportunity for IVD companies" and that "the *benefits* are pretty clear," Thermo Fisher is not enrolled, as *Medtech Insight* pointed out to him during the CFQ forum.

Shearstone explained Thermo Fisher's absence from the program he highly touts as "a matter of education" given that he has been a VP at the firm for only a year.

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

By Shawn M. Schmitt

09 Jul 2019 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. *Read the full article here*

"For me, with such a huge network, I really need to sit with the principles behind VIP and get a complete understanding of what it's going to take" to be part of the program, he said.

"Part of my challenge is moving my company toward proactivity, and if [CFQ VIP] can help do that, then I'd be hypocritical if I didn't embrace it," Shearstone added.