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Reimagining The 'Case For Quality': FDA Looking At More Hands-Off Approach, CDRH Director Shuren Says

by Shawn M. Schmitt

In an effort to step back some from its role as a ringleader for the Case for Quality initiative, US FDA wants to create a "collaborative community" so various industry stakeholders can have a say in the six-year-old scheme that aims to drive a quality mindset throughout device manufacturing organizations.

US FDA is looking to form a "collaborative community" to help it step back a bit from its role as a ringleader for the Case for Quality initiative it created six years ago, the head of the agency's device center says.

Center for Devices and Radiological Health Director Jeffrey Shuren claims that by taking a more hands-off approach, FDA would help strengthen the *Case for Quality*. The scheme – which the agency co-leads with the Medical Device Innovation Consortium (MDIC) – aims to change industry thinking from a compliance mindset to one of sustained quality throughout manufacturing organizations.

FDA views the Case for Quality "as a terrific opportunity for instantiating what we call a 'collaborative community,'" Shuren said Nov. 15 at an MDIC Case for Quality Forum in Washington, DC.

When there is a pressing issue in industry, "traditionally it is FDA that will go off and solve the problem. But over the past few years we have more and more pushed for [collaboration] with others," he said. Nevertheless, most solutions are still "very FDA-driven" and "very FDA-centric" – and "it's FDA ultimately making the call" anyway, Shuren said.

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But through a collaborative community, a variety of stakeholders – both in the public and government arenas – can have a say in developing solutions that address specific needs.


CDRH Director Jeffrey Shuren

"That is the mindset where we have been going – we're willing to make changes not simply because it's of value" to FDA, Shuren said. "Maybe it's not the most important thing to [the agency], but it is important to others that are out in the community. It's worth doing that because it pays off dividends for all of us."

The question is, he said: "Can we drive within Case for Quality ... that kind of collaborative community, where FDA is not the one driving it? Where it's not FDA-centric, but we simply have a seat at the table as a member of the community, and are willing to engage in that give-and-take?"

By launching a collaborative community for Case for Quality, best practices could be developed for "new tools and methods" that would promote quality practices, Shuren said, pointing out that it would "ultimately get us to a continuous learning system where ... we're identifying those practices and tools and methods."

And then, "let's assess and identify what works and what doesn't work through real-world experience, and then feed that back into the system," he said.

"So, that's what we're trying to achieve with Case for Quality. That is, in fact, the reimagining of the system."

Shuren Touts CMMI Pilot

Arguably the most ambitious Case for Quality work to date is designs to launch an FDA pilot program in January that will gauge the manufacturing maturity of device manufacturers.

Under the Voluntary Medical Device Manufacturing and Product Quality Program, the quality systems and manufacturing processes of participants

'Case For Quality' Finds Home In 'Super Office'

FDA announced in late September that it's building a new "super office" within CDRH that will essentially dissolve and replace the Office of Compliance, ODE, and the Office of

will be evaluated by third-party appraisers against the *Capability Maturity Model Integration* (CMMI) appraisal framework.

Results of a manufacturer's CMMI assessment will be shared with FDA; the agency will then use the information to help shape its regulatory, compliance and enforcement decisions. (Also see "*Quality On The Brain: FDA Maturity Pilot Aims To Shift Industry's Compliance Mentality To A 'Quality Mindset'*" - Medtech Insight, 29 Sep, 2017.)

FDA is aiming to accept at least 30 companies for the pilot, which will run during all of 2018. (Also see "*FDA Looks For Diverse CMMI 'Maturity' Pilot Enrollees; Device-Makers Expect Big Savings*" - Medtech Insight, 16 Oct, 2017.) Firms that take part will qualify for incentives such as waived pre-approval inspections and leeway on 30-day notice manufacturing-change submissions. (Also see "*Gifts For Industry: From Waived Inspections To Pre-Market Leeway, US FDA Woos Firms For Maturity Pilot*" - Medtech Insight, 25 May, 2017.)

"We're kind of saying, if you've gone through this appraisal and you rate very high on the maturity model, there are things in the FDA that we [can do to] help incentivize," Shuren said. "So, that will include opportunities for us to not conduct a pre-approval inspection [and to also] streamline 30-day notices. [Because] by the 30th day, there might have been multiple changes. So, let's package that together. Let's have a much more streamlined submission. And then we would do a review in about – here's what we're targeting – two business days."

In return, FDA would conduct a "quality check ... by doing periodic audits of those submissions. We really want to make this work less burdensome for everybody, and better target our resources," he said.

Surveillance and Biometrics. (Also see "*'Super Office' To The Rescue: FDA's Device Center Is About To Undergo A 'Total Product Life Cycle' Makeover*" - Medtech Insight, 29 Sep, 2017.)

Bill Maisel, the agency's deputy center director for science (and two additional *FDA "acting" titles*) will lead the new "Total Product Life Cycle" office, which will bring pre- and post-market experts together to provide the agency with better visibility of products, device-makers and various device classes from cradle-to-grave to help guide its pre- and post-approval decision-making.

In that TPLC super office, "Case for Quality will go under a structure we call 'Strategic Initiatives,'" CDRH Director Jeffrey Shuren said. "So, it will be driven at a very high level, and it will continue with me as the executive champion.

"Ultimately our goal is that [Case for Quality] becomes operationalized and it's incorporated into the DNA at CDRH – that it simply becomes day-to-day business," he added. "And, as we move forward, we will continue to have dedicated resources" for Case for Quality.

"Why modify our submission review? Well, we want to build an environment of trust – trust between FDA and industry – and then leverage that trust and sort of drive greater transparency on the part of manufacturers where essentially they're opening their operations up more but they're doing it in a much safer way," Shuren said.

"Ultimately what we're looking for is value to patients – that we have better product out on the market, and we're rewarding those companies that have that greater focus on quality."

From the editors of The Gray Sheet