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04 May 2022 | **News**

‘If You Know The Answer, Let Me Know’: FDA’s Shuren Mum On 1 Year Transition For Coming QMSR Reg

Industry groups and other stakeholders have requested more than a year to comply with the Quality Management System Regulation, when finalized

by Shawn M. Schmitt

Jeff Shuren, director of the US FDA’s device center, said on 4 May that the agency “thought it was enough time” when it proposed a one-year transition time frame from its current Quality System Regulation to the new Quality Management System Regulation.

The director of the US Food and Drug Administration’s device center, Jeff Shuren, said on 4 May that the agency “thought it was enough time” when it proposed what some consider a swift one-year transition from its current Quality System Regulation (QSR) to the new Quality Management System Regulation (QMSR).

The QMSR was released as a draft rule in late February. When finalized, it will replace the QSR, which has been the bedrock rule for making safe and effective devices in the US since the mid-1990s. The QMSR is a result of the agency’s years-long work harmonizing the QSR with international quality systems standard ISO 13485:2016. (Also see "*10 Things You Need To Know About FDA’s Proposed Quality Management System Regulation*" - Medtech Insight, 23 Feb, 2022.)

Industry advocacy groups including AdvaMed and the Medical Imaging & Technology Alliance told the FDA at a March public meeting on the QMSR that one year wouldn’t give some device makers enough time to make the switch

FDA’s Shuren On Why Agency Broke Up Its IVD And Radiological Health Office

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from one reg to another. Even the convener of the International Organization for Standardization (ISO) working group that oversees ISO 13485 told the agency at the time that some companies, big and small, will need at least an extra year. (Also see "*Industry To FDA: 1 Year Isn't Enough Time To Transition To New QMSR Rule*" - Medtech Insight, 2 Mar, 2022.)

By Shawn M. Schmitt

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The US FDA split its Office of In Vitro Diagnostics and Radiological Health in two earlier this week because it "really had two flavors of technology – actually three – that sat in there," says Jeff Shuren, director of the agency's device center.

Read the full article here

When asked by *Medtech Insight* at the AFDO/RAPS MedCon Conference 2022 whether 12 months was sufficient for transition, Shuren said stakeholder comments on the draft QMSR – *which will be accepted through 24 May* – will help the agency decide whether to allow for more transition time.

"We certainly thought it was enough time when we put it in the proposed rule," Shuren said. "We've seen comments on it. We're going through the comments. We'll see where we end up. What will be the final answer, even I can't tell you. It goes through a process, as people well know, and we'll see.

"But if you know the answer, let me know, and we can just cut to the chase right now. It will save me a lot of time."

> ***"There's going to be a lot of change likely between the proposed rule and the final rule." – Keisha Thomas***

At a separate 4 May MedCon session, Anne Reid, acting program director of the Office of Medical Devices and Radiological Health (OMDRHO) within the FDA's Office of Regulatory Affairs, said she isn't sure if one year is enough time or not.

"I'm going to take the position that Dr. Shuren took. I don't know the answer," she said. "We want to hear from you, we want to hear from our stakeholders. ...Please *read the regulation* and comment. You need to decide what's best for your particular situation and how you would feel about it if you had to do this. So you need to comment."

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Meanwhile, at a third MedCon session that same day, Keisha Thomas, associate director for compliance and quality for the FDA's Center for Devices and Radiological Health (CDRH), echoed statements by Reid and Shuren.

"We did hear a lot of comments at the [March] panel meeting regarding whether or not the proposed transition period of one year is enough, or whether that will remain the same. What I will say is … all of this is open," Thomas said.

"Your comments are useful and helpful," she added. "We have not made a final decision. What you have there is a proposed rule. There's going to be a lot of change likely between the proposed rule and the final rule, and a big part of that is … depending on comments."

Agency Needs Prep Time Too

Thomas went on, noting that it's not just industry that needs time to transition from the QSR to the QMSR. The FDA needs to prepare as well, she said.

"FDA has to do a lot of activities, which started [about two years ago] in the process of us developing and drafting this proposed rule, but we also have considerations … [like] updating IT systems and our technology systems, [and] training an entire cadre of staff," such as facility investigators, Thomas said.

The draft QMSR calls for the FDA to update its Quality System Inspection Technique. Investigators have used QSIT since 1999 to make sure they look at the most important compliance issues and ask pertinent questions linked to four major quality system subsystems during an audit.

The agency's draft quality system rule also pushes the agency to update internal policies, procedures, and industry guidance documents, as well as other satellite regulations that are called out by the current QSR.

> *"Training, training, training. We talk about training a lot. That includes basic ISO training for all of our staff." – Anne Reid*

And the FDA's Reid pointed out that it's also her office that needs adequate transition time. "Over at OMDRHO, we have to prepare for that. This is not a simple matter of, 'Hey, here's a rule change. Here's some new things in 21 CFR, [Part 820], let's go,'" she said. "No. This is going to be

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very transformative for the work that we do in OMDRHO."

21 CFR, Part 820 is the Quality System Regulation. Under the draft QMSR, the new reg will also be titled Part 820.

"A couple of years ago we had an implementation plan that we put together … and we stood up work groups. And we've been standing up work groups for at least three [years] to address what we're going to have to change in our program and our approach" because of the QMSR, Reid said.

"Some of these work groups [are looking at] … policy and procedures, and identifying things that need to be changed where the language has 820 language in it – we have to go back and put ISO language in there. So those things have been identified for change," she said.

Reid further said training is a key component to making the QSR/QMSR switch.

"Training, training, training. We talk about training a lot," she said. "That includes basic ISO training for all of our staff, in addition to very pointed and specific training for our compliance officers and CSOs," or consumer safety officers.

Another agency doc that needs to be updated is its FDA-483 inspectional observation form, given by investigators to companies upon the close of an inspection if violations were noted.

"We have a group that's just dedicated to working on that, and of course our inspection approach. That's going to have to change," she said. "I know all of you are accustomed to QSIT, [but] that's going to change."

FDA Wants To Communicate

The CDRH's Thomas said the agency will communicate with industry and other stakeholders throughout the transition process.

"This is going to be a continual, collaborative activity between us and our stakeholders, because what we want at the end of the day – because the change is significant – is to make sure we do it right, and doing it right is a hefty focus, and [an] intentional education and communication campaign as well," she said.

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