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Another Delay On The Way? FDA's Shuren Says Industry Should 'Anticipate' QSR Harmonization To Take 'Little While Longer'

Agency's device center director plays coy when asked if FDA will keep "Quality System Regulation" name

by Shawn M. Schmitt

Jeff Shuren, director of the US FDA's device center, signaled on 15 September that the agency might not have the hotly anticipated draft of its retooled Quality System Regulation ready for release by next month.

The director of the US Food and Drug Administration's device center signaled on 15 September that the agency might not have the hotly anticipated draft of its harmonized Quality System Regulation ready for release by next month.

The revised rule "remains a high priority for the center, but as you can imagine, with all the attention we've had ... on COVID-19, there are many other activities we could not devote the same level of engagement on. So anticipate that it will be a little while longer before we're able to issue the ISO 13485 [draft] regulation," Jeff Shuren said at RAPS Convergence 2020, hosted by the Regulatory Affairs Professionals Society.

The FDA has been harmonizing its QSR with international quality systems standard ISO 13485:2016 since 2018.

The agency in July set *October 2020* as the latest in-house target date for releasing the draft rule; the agency had previously set deadlines of *April 2019*, *September 2019* and *April 2020* for the release. (Also see "*FDA Sets (Another) Deadline For Releasing Draft Harmonized Quality System Regulation*" - Medtech Insight, 10 Jul, 2020.)

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"We will allow time for transition." – Jeff Shuren

Shuren wouldn't commit to a specific time frame for medical device manufacturers to transition to the new regulation, when finalized.

"In terms of implementation, just keep in mind that we will allow time for transition," he said, pointing out that industry will have plenty of time to review the draft rule as it goes through the public comment process and inevitable revisions, before a final rule is put out.

"You'll see in a proposed rule what we would plan to do, and that should be a starting point for folks to begin to make appropriate changes in their [quality] systems," Shuren said.

And for manufacturers that aren't in compliance with ISO 13485, the occasion of the draft regulation is "a good opportunity to get going, even though we are going to provide plenty of time to do so," he said.

The FDA's Melissa Torres said in June that industry should expect a "transition period of a few years" to the new QSR requirements. Torres is associate director for international affairs in the Center for Devices and Radiological Health, and is one of many at the agency working on the revised reg. (Also see "*Q&A: New Details Emerge From FDA About Long-Delayed Draft Rule That Harmonizes Quality System Reg With ISO 13485*" - Medtech Insight, 9 Jun, 2020.)

Meanwhile, when asked by *Medtech Insight* during the RAPS Convergence if the FDA's upcoming rule will keep the name "Quality System Regulation," Shuren played coy.

"That certainly has been a matter of discussion, and we appreciate that if we're doing something different, should it have a different moniker than what we currently have in place," he said.

Kim Trautman, who authored the QSR in the 1990s, said in July that the agency would be wise to change the reg's name.

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By Shawn M. Schmitt

15 Sep 2020
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(Also see "*QSR Author Kim Trautman: FDA Should Change Name Of New Quality System Reg (And Other Thoughts)*" - Medtech Insight, 13 Jul, 2020.)

The former FDAer, who's now executive VP of health sciences for consulting firm NSF International, suggested that the agency rename the retooled rule the "Quality Management System Regulation" to differentiate it from the current Quality System Regulation and the GMP regulation, which preceded the QSR.