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After QSR Delays, 'It's Full-Steam Ahead With That Proposed Regulation,' FDA's Shuren Vows

by Shawn M. Schmitt

Jeff Shuren, director of the US FDA's Center for Devices and Radiological Health, said on 6 May that the agency's efforts around harmonizing its Quality System Regulation with ISO 13485 are "back on track."

Jeff Shuren, director of the US Food and Drug Administration's device center, wants device makers to know that the agency's efforts around harmonizing its Quality System Regulation with ISO 13485 are "back on track."

Because of the coronavirus pandemic, "priorities like the regulation on formally adopting and transitioning to the ISO 13485 standard from our QSR ... [was] taking longer. I will tell you, [that effort] is back on track. [It's] moving forward and we're making great progress, and trying to get back to normal," Shuren said on 6 May at MedCon 2021, hosted by the FDA and Cincinnati's Xavier University.

The QSR is the bedrock rule for manufacturing safe and effective medical devices to be sold in the US, while ISO 13485:2016 is used by manufacturers to ensure quality systems compliance with regulators in a variety of countries.

The FDA has been harmonizing the QSR with the standard since 2018. The agency has set five internal deadlines since 2019 for releasing a draft of the proposed rule but has missed all of them. (Also see "*FDA Misses Fifth Target Date For Issuing Draft Harmonized Quality System Reg*" - Medtech Insight, 1 Mar, 2021.)

At MedCon, Shuren defended the amount of time the agency has taken to craft the draft rule.

"We want to make sure we do it right and have done the right crosswalk ... [between] the QSR

and the standard," he said. "And secondly, we got hit by COVID. That's the reality of it, and folks who were engaged in the regulation had COVID duties, and COVID's top priority. So things took a little bit longer.

"But as I mentioned, though, we're back on track. It's full-steam ahead with that proposed regulation," Shuren said. "I don't have a crystal ball on timing, simply because a lot of it's out of our hands, but our goal is it will happen this year. It's a top priority for us, and from our perspective, sooner is a heck of a lot better than later."

FDA's Shuren: 'Senior-Level Folks' Will Take Part In New Inspectional Affairs Council

By Shawn M. Schmitt

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US FDA device center director Jeff Shuren on 6 May shed a tiny bit of light on the agency's newly announced – but not defined – Inspectional Affairs Council.

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