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For FDA, The Third Time Wasn't The Charm For Releasing A Draft Of Its Harmonized Quality System Reg

by Shawn M. Schmitt

The US agency missed yet another internal deadline for publishing a draft of its revised Quality System Regulation. The FDA's April 2020 target for releasing a draft is the third one it failed to meet; it has been working on harmonizing the QSR with ISO 13485 since mid-2018.

The US Food and Drug Administration has missed yet another internal deadline for publishing a draft of its retooled Quality System Regulation. The agency has been working on harmonizing its QSR with international quality systems standard ISO 13485 since mid-2018.

The FDA's *April 2020 deadline* for releasing the draft is the third one it failed to meet. The agency had previously set target publish dates of *April 2019* and *September 2019*. (Also see "*Delayed Twice, FDA Now Says It Won't Release Its Harmonized QSR/ISO 13485 Draft Rule Until April 2020*" - Medtech Insight, 20 Nov, 2019.)

In March, FDA device center director Jeff Shuren strongly suggested that the agency wouldn't meet its latest April deadline, telling *Medtech Insight* at the time that the draft reg would come out "sometime" in 2020. (*See sidebar story.*)

But Shuren's comments came before the coronavirus pandemic began monopolizing the FDA's time.

In a recent email to *Medtech Insight*, FDA

FDA's Retooled Quality System Regulation Coming 'Sometime This Year,' CDRH Chief Shuren Says

By Shawn M. Schmitt

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In an exclusive interview with *Medtech Insight*, FDA device center director Jeff Shuren

spokesperson Jim McKinney said agency staffers are “balancing resources” in light of the COVID-19 crisis.

“We are continuing our work on the rule, time permitting, considering many of the agency’s resources are also currently engaged in COVID response activities,” he said.

The QSR has been the bedrock rule for manufacturing safe and effective medical devices to be sold in the US since the late 1990s, while *ISO 13485:2016* is used by device firms to ensure quality systems compliance with regulators in a variety of countries.

wouldn’t commit to meeting the agency’s internal deadline of April for putting out a draft version of its revised Quality System Regulation, which will be harmonized with international standard ISO 13485. Instead, he would only say that the rule would likely be out “sometime” in 2020...

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