MEDTECH INSIGHT
CITELINE COMMERCIAL

17 Nov 2020 | **News**

FDA Official Confirms 2021 For Release Of Draft QSR, Asks For 'Inclusive Comment Spectrum'

by Shawn M. Schmitt

The US FDA's Elizabeth Miller says the agency won't release a draft of its revised Quality System Regulation until sometime next year. The FDA has been harmonizing its QSR with international quality systems standard ISO 13485:2016 since 2018.

A draft of the US Food and Drug Administration's revised Quality System Regulation will be released sometime in 2021, an agency official confirmed on 17 November.

"Although delayed a bit from what was forecasted, FDA intends to publish the proposed rule for the transition of the medical device Quality System Regulation … to the ISO 13485:2016 standard in the Federal Register in 2021," said Elizabeth Miller, assistant commissioner of medical products & tobacco operations within the FDA's Office of Regulatory Affairs.

The agency has been harmonizing its QSR with international quality systems standard ISO 13485 since 2018. It has missed four internal deadlines for releasing a draft rule, the most recent of which was last month. (Also see "*As Expected, FDA Misses Fourth Consecutive Deadline For Releasing Draft QSR*" - Medtech Insight, 1 Nov, 2020.)

Outside observers suggested in recent months that the FDA would probably put off issuing the draft QSR until 2021. (Also see "*HHS Secretary's Regs Sign-Off Requirement Will Kick FDA's Draft QSR Into 2021, Expert Predicts*" - Medtech Insight, 23 Sep, 2020.)

> *"The more inclusive the comment spectrum, the better the final rule." – Elizabeth Miller*

When the draft is finally released next year, the agency is looking forward to robust stakeholder feedback, Miller said.

"Remember, this Federal Register notice [will be] the opportunity for all stakeholders to provide comments on the proposed rule," she said. "Comments from all types of stakeholders – small, medium and large firms; firms currently certified to the ISO standard and those that are not, or never have been certified to the standard; consultants who work with broad spectrums of firms; start-up companies and longtime veteran companies.

"The more inclusive the comment spectrum, the better the final rule."

Miller's comments came during FDAnews' 15th Annual Inspections Summit.