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Updated FDA Reg Agenda Says New QSR Will Come This Month – But There's Cause For Skepticism

by Shawn M. Schmitt

The US FDA has indicated that it intends to release a draft of its harmonized Quality System Regulation by the end of the year. But time is running out, and the agency has scheduled the draft's release six other times since 2019.

The US Food and Drug Administration has *updated its official regulatory agenda* to indicate that it will release a draft of its new harmonized Quality System Regulation sometime this month.

But time is running out – it's already 22 December – and the FDA has scheduled the draft's release six other times since 2019. The bottom line? Industry should take the agency's latest scheduling with a massive grain of salt. (Also see "*FDA's Draft QSR: 'Lucy' Pulled The Football Away. Again*" - Medtech Insight, 1 Jul, 2021.)

The FDA has been harmonizing its Quality System Regulation with international quality systems standard ISO 13485:2016 since early 2018. The QSR has been the bedrock rule for manufacturing safe and effective medical devices to be sold in the US since the mid-1990s, while ISO 13485 is used by device firms to ensure quality systems compliance with regulators in a variety of countries.

The director of the FDA's device center, Jeff Shuren, said earlier this year that the draft QSR would come in 2021, but roughly two months ago he signaled that the agency's end-of-year goal would probably be missed. (Also see "*Will FDA Release Its Draft Quality System Reg This Year? All Signs Point To No*" - Medtech Insight, 5 Nov, 2021.)

The rule "is a big priority for us," Shuren said in mid-October at the AAMI/FDA/BSI Virtual International Conference on Medical Device Standards and Regulation. "You know, it's our hope

that [the draft rule] will see the light of day in the coming months."

In episode three of Medtech Insight's podcast series Speaking Of Medtech, Steve Silverman, a former director of the FDA device center's compliance office, said he'd be surprised if the draft rule is out by the end of this month.

"There are so many factors in play, like FDA's ongoing pandemic response, the fact that there's still no FDA commissioner, and device user-fee negotiations are ongoing. With all of these factors in place, I'd be amazed to see a draft rule this year," said Silverman, who's now head of The Silverman Group consulting firm.

"At the same time, there's no rush here in reality," he added. "In the US we have a stable system, the QSR. And the rest of the world can continue with ISO 13485. Yes – maintaining these two models is inefficient, but it's an inefficiency that's been in place for decades." (Also see "*Speaking Of Medtech, Ep. 3: FDA Quality System Regulation Harmonization*" - Medtech Insight, 3 Nov, 2021.)