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Delayed Twice, FDA Now Says It Won't Release Its Harmonized QSR/ISO 13485 Draft Rule Until April 2020

by Shawn M. Schmitt

First it was April 2019, then September 2019 – but both of those deadlines were missed. Now, the US agency has set a target date of April 2020 to release a draft regulation that will harmonize its Quality System Regulation (QSR) with international standard ISO 13485.

The US Food and Drug Administration has once again pushed back its deadline for delivering a draft version of a new rule that will harmonize its Quality System Regulation (QSR) with international standard ISO 13485.

The agency has updated its *official regulatory agenda* to note that the draft regulation won't be ready until April 2020.

The FDA's QSR has been the bedrock rule for manufacturing safe and effective medical devices to be sold in the US for more than two decades. Meanwhile, *ISO 13485:2016* is used by device firms to ensure quality systems compliance with regulators in a variety of countries, including Canada, Japan, Australia and the 28 member states of the EU.

The FDA *announced in May 2018* that it would update the QSR. A draft of the rule was to be released by the agency in *April 2019* but that didn't happen. A second target date of *September 2019* was also missed.

A longtime industry expert familiar with the FDA's thinking on the subject told *Medtech Insight* in late September that the rule had been held up because of "disagreements technically on the inside" of the agency. "The draft proposal is still in quite a flux," the source added. (Also see "*QSR/ISO 13485 Harmonization Update: FDA Enforcement Discretion Likely When New Rule Stands Up; Draft Reg Coming By Year's End*" - Medtech Insight, 26 Sep, 2019.)