MEDTECH INSIGHT
CITELINE COMMERCIAL

22 Feb 2022 | **News**

BREAKING: FDA Releases 'Quality System Regulation Amendments' Draft Rule

by Shawn M. Schmitt

After nearly four years of work, the US FDA has issued its new draft rule, "Medical Devices; Quality System Regulation Amendments." If finalized, the QSR reg will be renamed the "Quality Management System Regulation," or QMSR.

After nearly four years spent retooling its Quality System Regulation – 21 CFR, Part 820 – the US Food and Drug Administration on 22 February finally released its draft rule that harmonizes the QSR with ISO 13485:2016.

"While the current QS regulation provides sufficient and effective requirements for the establishment and maintenance of a quality management system, regulatory expectations for a quality management system have evolved since the regulation was implemented over 20 years ago," the agency says of its 52-page draft, "*Medical Devices; Quality System Regulation Amendments*."

If finalized, the QSR reg will be renamed the "Quality Management System Regulation," or QMSR. Interestingly, longtime industry expert and ex-FDAer Kim Trautman, who was the lead author of the QSR in the 1990s, *suggested to Medtech Insight in July 2020* that the agency rechristen the QSR as the Quality Management System Regulation to avoid confusion. (Also see "*QSR Author Kim Trautman: FDA Should Change Name Of New Quality System Reg (And Other Thoughts)*" - Medtech Insight, 13 Jul, 2020.)

The FDA has been harmonizing its Quality System Regulation with international quality systems standard ISO 13485 since early 2018. The agency says the draft, "if finalized, would harmonize quality management system requirements for devices with requirements used by many other regulatory authorities around the world."

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 FDA's release of its draft rule comes a mere 11 days after the White House Office of Management and Budget completed a review of the reg. (Also see "*OMB Completes Review Of FDA's Draft Harmonized Quality System Regulation*" - Medtech Insight, 9 Feb, 2022.)

[Editor's note: Medtech Insight *is reviewing the new draft rule and will file more reports in the coming days with expert industry commentary.*]

10 Things You Need To Know About FDA's Proposed Quality Management System Regulation

By Shawn M. Schmitt

23 Feb 2022

Longtime industry experts Kim Trautman and Eric Henry highlight some of the more important takeaways from the US FDA's draft rule that would create a new Quality Management System Regulation, or QMSR, to replace its current Quality System Regulation.

Read the full article here