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International Harmonization Has Arrived! FDA Issues Much Anticipated Revamp Of Quality System Regs

by Brian Bossetta

The US FDA has completed the final rule that will harmonize its decades-old quality system regulations with international standards. The new Quality Management System Regulation aims to reduce the regulatory burden on device makers by linking domestic and international requirements.

The Food and Drug Administration has released its final rule aligning its quality system regulation with the accepted international standard.

With its *final rule*, to be published in the Federal Register on 2 February, the agency's Quality Management System Regulation, or QMSR, replaces the old Quality System Regulation, or QSR.

The agency says the new framework will ensure medical devices are "safe, effective and of good quality" while making it easier for those devices to come to market, as manufacturers will only have to adhere to one regulatory standard for multiple markets.

Device manufacturers and importers now have two years — until 2 February 2026 — to modify their quality systems to meet QMSR. Until then, manufacturers must comply with the existing quality systems. This is a major change from the draft, which would have put the rule into effect after just one year.

Specifically, by replacing QSR with the revamped QMSR, the agency is marrying FDA quality regulations to the 2016 version of ISO (International Organization for Standardization) 13485 – an international quality standard first published in 1996 then revised in 2003 and again in 2016.

Linking QMSR to ISO 13845:2016 means device makers will only have to meet one regulatory quality standard for most international sales, rather than two. Device manufacturers in many

countries use the ISO as the benchmark for quality assurance, while the current QSR has been the regulatory foundation US regulators have relied on for ensuring the safety and efficacy of medical devices since the mid-1990s.

> *"By harmonizing key areas of a medical device manufacturer's quality management system with the international standard, the FDA is streamlining actions device manufacturers must take to meet requirements by multiple regulatory authorities." — Jeff Shuren*

Steve Silverman, president of The Silverman Group, told *Medtech Insight* he sees QMSR as a win-win and that the FDA deserves credit for pulling off a "massive lift" in getting the final rule across the finish line.

"The announcement of the final version of the QMSR is a victory for the FDA and the device community because it promotes a single, rational, and effective regulatory framework for device oversight," Silverman said. "As important, the FDA is acting responsively to stakeholder input by adopting a manageable implementation timeline."

Since the FDA released its proposed rule on QMSR in February 2022, the agency remained steadfast that it would publish a final rule by the end of 2023. And while it missed that mark by a month, the publication of the final rule ends a harmonization process the FDA has been working on since early 2018. (Also see "*Christmas Is Coming, But Will There Be International Harmonization?*" - Medtech Insight, 14 Dec, 2023.)

The QMSR rule, the FDA says, emphasizes risk management activities and risk-based decision making while lessening regulatory burdens.

"By harmonizing key areas of a medical device manufacturer's quality management system with the international standard, the FDA is streamlining actions device manufacturers must take to meet requirements by multiple regulatory authorities," said Jeff Shuren, director of the FDA's Center for Devices and Radiological Health.

The FDA has also held that international harmonization would result in getting safe and effective medical devices to patients more quickly and that adapting to the new standard should not be overly tasking for device makers.

"We have determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective," the final rule states.

> *"Device manufacturers run global operations, they think about the production and distribution of devices from a global perspective. And this approach aligns with that." — Steve Silverman*

Further, QMSR, the FDA says, will net significant savings, as much as $532m in annualized net costs at a 7% discount rate and approximately $554m in annualized net cost savings at a 3% discount rate.

"In addition to the cost savings to the medical device industry, the qualitative benefits of the rule include quicker access to newly developed medical devices for patients leading to improved quality of life of the consumers," the FDA says.

The FDA also emphasizes the need for the new standard due to the similarities of the ISO and QSR. Having to comply with both standards creates unnecessary redundancy for manufacturers, the FDA says, leading to inefficiency.

With just one standard, the FDA expects reduced workloads on industry — for example, less time will be needed to prepare documents and records for inspections and audits.

"In addition, the final rule will result in establishments conducting internal audits and management reviews based on aligned requirements as opposed to auditing and assessing separately to comply with the requirements of the previous QS regulation and ISO 13485 individually," the rule states.

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

The FDA says it incorporated numerous comments from various stakeholders as it completed its work. The final draft includes 83 comments submitted on the proposal with the agency's responses.

But while Silverman said a single system means device manufacturers have less responsibility for recognizing and satisfying competing regulatory systems — "which is a good thing" — what is more interesting and compelling about QMSR, in his view, is that it recognizes that the device industry operates in a global marketplace.

"Many device manufacturers run global operations, they think about the production and distribution of devices from a global perspective. And the QMSR aligns with that," Silverman said. "The FDA is also thinking globally about integrated systems that reflect other regulators whose views need to be accounted for. It's not just the FDA acting in isolation."