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US FDA Commissioner: Agency Will Propose New Rule That Blends Quality System Regulation, ISO 13485

by Shawn M. Schmitt

Scott Gottlieb wrote in a May 9 blog post that the agency will propose a new rule that will blend its Quality System Regulation with international quality systems standard ISO 13485. Gottlieb claims the new rule would "harmonize domestic and international requirements, and modernize the regulation," while making sure that device-makers "adhere to high, internationally accepted quality systems."

US FDA will propose a new rule that will blend its Quality System Regulation with international quality systems standard ISO 13485, agency Commissioner Scott Gottlieb wrote in a May 9 *blog post*.

"As part of our efforts to continue to ensure efficiency of existing regulations, we will be taking another step to modernize medical device regulation by proposing a new regulation to replace certain aspects of existing Quality System regulations with specifications of an international consensus standard for medical device manufacturers (ISO)," Gottlieb wrote.

> ***The new "rule, if finalized, will harmonize domestic and international requirements, and modernize the regulation," FDA head Scott Gottlieb wrote.***

ISO is the *International Organization for Standardization*; device-makers use its *ISO 13485* to

ensure quality systems compliance with regulators in a variety of countries, including Canada, Japan, Australia and the 28 member states of the European Union.

Gottlieb also wrote that the new "rule, if finalized, will harmonize domestic and international requirements, and modernize the regulation to make it more efficient for manufacturers of medical devices seeking to sell their products globally, while also continuing to ensure they adhere to high, internationally accepted quality systems."

FDA also added the redo of the Quality System Regulation to the agency's *official regulatory agenda*.

ISO 13485 was *last revised in 2016*; manufacturers that use the standard *have until March 1, 2019*, to become fully certified to the latest version or risk enforcement action.

There were rumblings of late in industry that FDA would swap out the QSR – *21 CFR Part 820* – with ISO 13485. And, on May 3 at MedCon 2018 in Cincinnati, Sean Boyd, deputy director for regulatory affairs for the Office of Compliance within FDA's Center for Devices and Radiological Health, *confirmed that the rumors were true* – that the agency was indeed considering how it could "better converge and move toward the use of ISO 13485 potentially in lieu of" the QSR. (Also see "*Bye-Bye QSR? FDA May Swap Its Quality System Regulation For ISO 13485 'In The Coming Years,' Official Says*" - Medtech Insight, 4 May, 2018.)

Gottlieb's post, however, suggests that the agency will be cherry-picking parts from the standard and the QSR to create a whole new regulation, rather than simply swapping the two out.

Regardless of how it's done, it would be a long-term project for the agency, Kim Trautman, executive VP of medical device international services at NSF International, told *Medtech Insight* in a May 2 interview at MedCon. (Also see "*NSF's Trautman Talks MDSAP, Swapping FDA's QSR For ISO 13485, Regulatory Convergence, EU's MDR & IVDR, And More*" - Medtech Insight, 9 May, 2018.)

"It doesn't matter what the changes are. The same rulemaking promulgation practices need to be followed as dictated for all federal agencies," she said. That includes scheduling public comment periods and collecting comments, and performing economic impact analyses, among other tasks.

Check out what Trautman – an ex-FDA official who wrote the Quality System Regulation in the 1990s – had to say about FDA's plan to change its QSR in the podcast below, beginning at the 17:26 mark:

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