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FDA Official: QSR/ISO 13485 Mash-Up On Track But Will 'Take Time'; CDRH's Shuren Open To 'Adopting More Standards'

by Shawn M. Schmitt

The US FDA's plan to harmonize its Quality System Regulation with ISO 13485 is rolling along despite one FDA official's recent claim that only a "limited number of staff" are acquainted with the international quality systems standard. Meanwhile, CDRH Director Jeff Shuren says the medtech industry should "anticipate" that the agency will increasingly recognize more standards.

A plan by the US Food and Drug Administration to harmonize its *Quality System Regulation* with ISO 13485 is rolling along despite one FDA official's recent claim that only a "limited number of staff" are acquainted with the international standard.

In a blog post exactly one year ago, then-FDA Commissioner Scott Gottlieb announced that the two documents would be merged, and the agency soon after *added the QSR redo to its official regulatory agenda*. (Also see "*US FDA Commissioner: Agency Will Propose New Rule That Blends Quality System Regulation, ISO 13485*" - Medtech Insight, 9 May, 2018.)

Device-makers use *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.

"We have a target of this year to publish a notice of proposed rulemaking that would describe the specific steps we anticipate taking to adopt ISO 13485, so stay tuned," said Sean Boyd, director of the Office of Regulatory Programs in the FDA's device center. ORP sits within the Center for Devices and Radiological Health's new Office of Product Evaluation and Quality (OPEQ). (Also see "*Day 1: US FDA Launches New 'Super Office,' Says It's Already Proven Its Worth*" - Medtech Insight, 1 May, 2019.)

"Later this year we'll be able to provide some more detail of what we think we need to do and how we will kind of continue along this journey to manage that transition," Boyd said on 2 May at MedCon 2019, held at Cincinnati's Xavier University.

And in a 9 May email to *Medtech Insight*, Boyd said "FDA intends to provide more information in 2019 around its specific plans to align its QS requirements with ISO 13485, at which time there will be opportunity for public comment on our proposed approach."

> ***"This will be a big transition for FDA, especially when you think about everything that we've built around the Quality System Regulation." – Sean Boyd***

At MedCon, Boyd admitted that "this will be a big transition for FDA, especially when you think about everything that we've built around the Quality System Regulation, such as the Quality System Inspection Technique that our investigators perform."

He added: "We have a limited number of staff who are familiar with ISO 13485 right now."

The *Quality System Inspection Technique* – QSIT – is designed to make sure that FDA investigators look at the most important compliance issues and ask pertinent questions linked to four major quality system subsystems: management controls, corrective and preventive action (CAPA), design controls, and production and process controls.

Combining the QSR with ISO 13485 "will require adaptation of the Quality System Inspection Technique that we use today, and it will require training of our staff to get them familiar with the requirements that we're moving toward," Boyd said.

"So, we anticipate this taking time, and we anticipate working with industry over the course of that time."

> ***"It would be much more straightforward if we could just all be on ISO." – Jeff Shuren***

CDRH Director Jeff Shuren said on 1 May at MedCon via video link that the mash-up of the two documents "will allow us to be harmonized with much of the rest of the developed world."

Despite Boyd's insistence that harmonization efforts won't happen overnight, Shuren said the lift won't be horribly heavy given that "our current Quality System Regulation and the current version of 13485 are very close. There's only a handful of differences. We've done that crosswalk."

QSR Challenges Include MDSAP Audit Results

Solely using the QSR, Shuren said, can sometimes be a challenge for the agency as more regulators around the world edge ever closer to adhering to ISO 13485. For example, agency officials sometimes find it difficult to review a manufacturer's results from a Medical Device Single Audit Program audit.

That's because MDSAP – which allows firms to undergo one audit by an accredited third party to satisfy quality regulations for the US, Canada, Brazil, Japan and Australia – maps to ISO 13485. (Also see "*MDSAP Is A Snap If Your Firm Follows Quality Systems Standard ISO 13485, Auditor Says*" - Medtech Insight, 31 Jan, 2019.)

A Combo, Not A Replacement

The FDA's Sean Boyd confirmed to *Medtech Insight* on 9 May that the two documents will indeed be combined, and that ISO 13485 will not supplant the QSR.

"FDA expects to adopt ISO 13485 in place of requirements that are reflected both in the regulation and in the ISO standard," he explained. "Components of Part 820 [the QSR] that are not reflected in ISO 13485 may remain to ensure FDA-specific requirements continue to be met."

The QSR "creates some challenges in reviewing particular [MDSAP] audits so that they line up with our needs," Shuren said. "It would be much more straightforward if we could just all be on ISO."

Shuren advises device-makers to continue with business as usual while the FDA works to combine the two documents.

"In the interim, there isn't anything [firms] would do or change from a documentation standpoint because we're only in a position to accept what lines up with our Quality System Reg," Shuren said.

Expect More Standards For FDA, Shuren Says

While the CDRH director says industry should "anticipate" that the agency will increasingly recognize more standards, Shuren noted that many standards aren't adopted by the FDA because they're not "regulatory-grade."

"They're not sufficiently robust enough that we could rely upon them in a meaningful manner," he said.

Shuren pointed out that an International Medical Device Regulators Forum (IMDRF) *working group* has been tasked with identifying best ways to make all standards more regulator-friendly.

"The voice of the regulator many times is not there in standards, or it's not strong," Shuren said.

QSR Author Kim Trautman Predicts What A Mash-Up Of FDA's Quality System Regulation And ISO 13485 Might Look Like

By Shawn M. Schmitt

15 Aug 2018

US FDA will face high hurdles as it works to write a new rule that would merge the agency's Quality System Regulation with international quality systems standard ISO 13485. That's according to Kim Trautman, a longtime industry insider who wrote the QSR in the early to mid-1990s. "It’s a clear heavy lift from a regulatory policy perspective" that could take...

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Therefore, he said, the agency has "engaged" with the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) to make sure the regulatory voice "is heard loud and clear."

"I think that effort will lead to the US FDA adopting more standards," Shuren said. "The hope is that it's going to lead to other jurisdictions adopting the same standards and hopefully approaching them ultimately in the same way."

Shuren went on to slightly bemoan the agency's level of participation in standards work, saying more could be done.

"Looking forward, it would be great if the device center had a larger investment, and we had more capability and more people [involved] in advancing that standards work," he said.

Nevertheless, "about 25% of the staff at CDRH are involved in one way, shape or form in ... over 630 standards development committees. So, our footprint is huge, but so much more needs to be done."