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FDA's Quality System Regulation Is Mapped To International Standard ISO 13485 – And Vice Versa – In New Report From AAMI

by Shawn M. Schmitt

A new Technical Information Report (TIR) from the Association for the Advancement of Medical Instrumentation compares regulatory requirements found in the US FDA's QSR to those in quality systems standard ISO 13485:2016. While the 146-page document is aimed at US device-makers, it could also be helpful to the FDA as the agency works to harmonize its QSR with the ISO standard.

A new Technical Information Report (TIR) from the Association for the Advancement of Medical Instrumentation (AAMI) compares regulatory requirements found in the US Food and Drug Administration's Quality System Regulation to those in international standard ISO 13485 – and vice versa.

AAMI TIR102:2019, released on 30 August, aims to help befuddled US device-makers that operate under the QSR ensure they're compliant with the standard from the International Organization for Standardization (ISO).

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 European Union. The standard also serves as the regulatory base for the burgeoning Medical Device Single Audit Program (MDSAP), which allows firms to undergo one audit by an accredited third party to satisfy quality regulations in five different countries. (Also see "*MDSAP Is A Snap If Your Firm Follows Quality Systems Standard ISO 13485, Auditor Says*" - Medtech Insight, 31 Jan, 2019.)

Former FDAer Kim Trautman, who authored the QSR in the 1990s, weighed in on AAMI's new TIR *on LinkedIn*, noting that it's "an officially recognized mapping tool for the medical device

global industry."

Trautman, who is now executive VP of medical device international services for consulting firm NSF International, added that "the mapping tool is bi-directional to assist in identifying the regulatory requirements in [the] Quality System Regulation to be addressed through an ISO 13485-compliant QMS [quality management system]."

But the TIR will also be helpful for the FDA, she wrote, as the agency works to harmonize its Quality System Regulation with the ISO standard. The FDA *announced in May 2018* that it would update the QSR, with a draft of the revised rule *coming this month*.

Trautman, who is part of an AAMI quality systems workgroup that developed the TIR, has long maintained that merging the QSR with ISO 13485 will be an uphill climb for the FDA that could take years to complete. (Also see "*QSR Author Kim Trautman Predicts What A Mash-Up Of FDA's Quality System Regulation And ISO 13485 Might Look Like*" - Medtech Insight, 15 Aug, 2018.)

Key Considerations And A Crosswalk

The "Key Considerations" section of the 146-page TIR "discusses notable differences between the QS Regulation and ISO 13485:2016," the document says. "This part also includes narrative relative to any systemic differences between the [QSR and the standard], which may have impact beyond a specific section."

The so-called key considerations include information on training and competence; approvals versus signatures; risk management; and corrective and preventive action (CAPA) versus improvement process.

The TIR also includes two tables mapping the QSR to ISO 13485, and vice versa.

The QSR/ISO 13485 Maze: How FDA's Satellite Device Rules Will Complicate A Quality System Regulation Rewrite

By Shawn M. Schmitt

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Kim Trautman, who authored the Quality System Regulation in the 1990s, says US FDA officials tasked with retooling the QSR will have to consider an array of other device-related rules that address complaints, product recalls and traceability – just to name a few – to make sure those requirements will still be met by manufacturers.

Read the full article here

"The mapping is provided in two directions purposefully," the document says. "When evaluating the two quality management systems, the full intent and similarities can only be determined by comparing in both directions. Therefore, both tables should be reviewed in their entirety."

The TIR points to differences in approach to vendor quality agreements in the QSR (under supplier controls) and the ISO standard (under outsourced suppliers and purchasing controls) as an example for why it's important to understand the two-way mapping.

"While there are no incongruities among the requirements for the quality management systems, there may be some verbiage or directed differences. This difference may not have been noticed reviewing the requirements in only one direction," the TIR explains.

"The requirements of both the QS Regulation and ISO 13485:2016 require quality agreements and allow a risk-based approach to meet this requirement (ie contracts, purchase orders, drawings or specifications)," the document continues. "The requirements of both [the QSR and the standard] can be met with flexible risk-based solutions and fulfill the obligation of both quality management systems."