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US Regulatory Roundup, June 2020: FDA Talks QSR Redo; ISO Risk Standard Gets Companion Doc; Experts Predict Recalls Surge; And More

by Shawn M. Schmitt

News out of the US FDA on the harmonization of its Quality System Regulation with ISO 13485, as well as stories on a new ISO technical report on risk management and a warning from experts about probable recalls because of the COVID-19 pandemic, were of most interest to our readers last month. Here are June's 10 most popular US regulation and policy stories from *Medtech Insight*.

QSR Update

News from a US Food and Drug Administration official that the agency will give medical device manufacturers "years" to comply with a retooled Quality System Regulation was the story of most interest to *Medtech Insight* readers in June.

Melissa Torres, associate director for international affairs in the FDA's Center for Devices and Radiological Health, said during an early June webinar hosted by the Association for the Advancement of Medical Instrumentation (AAMI) that "there will be a transition period of a few years to these new [QSR] requirements."

The FDA has been harmonizing its QSR – the bedrock rule for manufacturing safe and effective medical devices to be sold in the US since the late 1990s – with international quality systems standard ISO 13485:2016 for more than two years. ISO 13485 is used by device firms to ensure quality systems compliance with regulators in a variety of countries, including Canada, Japan, Australia, the UK and the 27 member states of the EU.

Torres offered a handful of insights into the QSR revision, including an "estimate" that a draft version of the harmonized regulation will be released this year. She also answered six questions about the process, ranging from how drug-device combination products will fare under the new QSR to the FDA's plan for retraining its facility investigators – and more.

TR 24971 Finally Arrives

The International Organization for Standardization (ISO) in mid-June issued a long-awaited companion document to its updated risk management standard for the device industry. The publishing of Technical Report 24971:2020 came roughly a half year after ISO 14971:2019 was released. ISO 14971 instructs companies on how to best put together a risk management program.

In our No. 2 story from last month, we explain how TR 24971 follows the same structure and clause numbers as ISO 14971, making it easier to read and apply. The revised TR also includes eight annexes that cover an array of information on risk management-related topics, including the identification of hazards, risk analysis techniques and risk acceptability considerations, as well as guidance for firms that make *in vitro* diagnostics.

COVID-19 Roundup

Our rolling COVID-19 coverage was also of high interest to readers in June. Popular stories centered on:

- Enforcement and product safety: *Experts warned that the medtech industry should brace for a wave of product recalls and US regulatory enforcement actions* as a result of the FDA's relaxed approach to compliance and wide distribution of emergency use authorizations (EUAs) during the pandemic.

- Legislation: US senators have been churning out bills to address different problems created by the coronavirus crisis. *We highlight five of them in this article*.

- Fraud: *Chinese manufacturer King Year Packaging and Printing Co. Ltd. is facing federal charges* for allegedly having shipped almost half a million misbranded and defective masks to the US. The masks were falsely purported to be N95 respirators.

- Transformations at the FDA: *Changes made by the agency in response to the pandemic may be here to stay*, commissioner Stephen Hahn said in mid-June. One element of the FDA's COVID-19 response that Hahn foresees carrying forward is a greater interdependence between regulators and industry, as the two collaborate to develop and collect data needed to safely regulate devices.

- "Testing Czar" concerns: Patty Murray, a Washington State senator who's a key member of

an important Senate health panel, *complained in early June that a decision by US Public Health Service Admiral Brett Giroir to step down* as the Coronavirus Task Force's "Testing Czar" will leave in the lurch college students who'll need testing.

Other Articles Of Interest

Stories about a high-risk Medtronic recall, an update to the corrective and preventive action (CAPA) process, and changes to the FDA's form for reporting adverse events rounded out our Top 10 list in June:

No. 4 story: After reporting almost a dozen injuries, a problematic function on Medtronic's StealthStation DBS software – used to give surgeons a 3D image of a patient's brain during deep brain stimulation (DBS) procedures – was designated as a class I recall. It's the second time the company has had to recall faulty software on its StealthStation in the past two years.

No. 7 story: An ongoing pilot program from the Medical Device Innovation Consortium, under the umbrella of the popular FDA/MDIC Case for Quality, is attempting to address industry's long-running problems with CAPA.

No. 10 story: An update by the FDA to its MedWatch 3500A adverse event reporting form targeted summarized events and patient gender. The agency will also update its electronic Medical Device Reporting (eMDR) system to accommodate the changes made to the 3500A, among other revisions.

The 10 most popular US regulation and policy stories in June are listed in the table below.

Rank	Story
1	*Q&A: New Details Emerge From FDA About Long-Delayed Draft Rule That Harmonizes Quality System Reg With ISO 13485*
2	*At Long Last, ISO Publishes Risk Management Standard Companion Doc TR 24971*
3	*Expect Surge In Recalls, Enforcement Actions When FDA's Soft Touch Ends, Inspections Resume, Experts Warn*
4	*Medtronic Brain Imaging Software Recalled After 11 Injuries*
5	*Senate Bills Would Require More COVID-19 PPE, US Manufacturing Capacity, Use Of Analytical Imaging*
6	*Chinese Manufacturer Charged With Distributing Phony N95 Masks*
7	*Not Your Grandfather's CAPA: Case For Quality Pilot Gives Corrective And Preventive Action A Facelift*
8	*Hahn: FDA May Keep Some COVID-19 Reforms Post-Pandemic*
9	*Decision By US COVID-19 Testing Czar To Step Down Critiqued By Key Health Panel Senator*

10	*FDA Tweaks 3500A Form For Reporting Adverse Events, Plans September Changes To eMDR System*