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US Regulatory Roundup, September 2019: QSR/ISO 13485 Mash-Up, FDA Commissioner News, New Guidance Docs, And More

by Shawn M. Schmitt

The latest news on the FDA's work to harmonize its Quality System Regulation with international quality systems standard ISO 13485 captured the attention of many of our online readers last month, as did stories about an upcoming pick by President Trump to fill the agency's top spot as commissioner and a slew of new, draft and updated guidance documents. Here are September's 10 most popular US regulation and policy stories from *Medtech Insight*.

The US Food and Drug Administration now has a handy tool at its disposal that it can use as it works to harmonize the Quality System Regulation – the bedrock rule for manufacturing safe and effective medical devices to be sold in the US for more than two decades – with international quality systems standard ISO 13485.

Our story on that tool, a new Technical Information Report (TIR) from the Association for the Advancement of Medical Instrumentation (AAMI), was of most interest to *Medtech Insight*'s online readers last month. *AAMI TIR102:2019* compares regulatory requirements found in the QSR to those in ISO 13485:2016 – and vice versa. Aside from being a useful resource for the FDA, the TIR aims to help befuddled US device-makers that operate under the QSR ensure that they're compliant with the standard from the International Organization for Standardization (ISO).

The FDA *announced in May 2018* that it would update its QSR. While the agency's *official regulatory agenda* said it would release a draft of the merged QSR/ISO 13485 rule in September, that did not happen. Instead, industry can likely expect the draft regulation to come by year's

end because of "disagreements technically on the inside" of the FDA, an industry insider close to the situation and familiar with the agency's thinking told *Medtech Insight*.

In our No. 3 story from last month, the insider noted that "the draft proposal is still in quite a flux," while FDA device center director Jeff Shuren said the agency is "looking to make this [transition to a new US rule] least burdensome as possible." Such flexibility on the part of the FDA likely means it will exercise enforcement discretion when the draft rule becomes final. Such discretion would give manufacturers and field investigators alike time to become accustomed to the new regulation's requirements.

Meanwhile, news that President Trump had narrowed his search for a new FDA commissioner to three people – current acting commissioner Ned Sharpless, Harvard University dermatology professor Alexa Boer Kimball and MD Anderson Cancer Center radiation oncologist Stephen Hahn – was *Medtech Insight*'s *second most-popular story* in September. *Recent media reports indicate*, however, that Hahn is strongly favored to take the position full time.

Also last month, the FDA released a slew of new, draft and updated guidance documents. Our stories on a few of those guidances – for the agency's 510(k) program and issues related to benefit-risk – ranked Nos. *4*, *6* and *7* on our top 10 list.

And *in our No. 5 story*, we detailed a rumble between device industry advocacy group AdvaMed and the *Atlanta Journal-Constitution* over concerns that sterilizing products by using ethylene oxide (EtO) is harmful to people and the environment. While lawmakers, regulators and journalists have been raising the alarm over the risk of cancer from excess EtO emissions, a toxicologist representing device-makers via AdvaMed said the concerns are not based on valid science.

Two sterilization facilities in Illinois and Michigan were shut down earlier this year because of concerns regarding potential high levels of EtO detected in the surrounding environment, and more recently, the residents of Smyrna and Covington in Georgia raised concerns about living in close proximity to two EtO sterilization facilities. The issue has put pressure on lawmakers and regulators to act, and the companies running the facilities agreed to spend millions to capture more EtO emissions released from their plants.

And speaking of AdvaMed, its chair Kevin Lobo – who is also CEO of medtech giant Stryker Corp. – says another moratorium on the 2.3% device excise tax is far more likely than a full repeal. “The likelihood for full repeal I think is fairly low given just the political dynamics at play, but I think a multiyear suspension is probably the most likely scenario,” Lobo said at the MedTech Conference in Boston, *in our No. 9 story* from last month.

Rounding out the top 10 list is a pair of articles about data. *Our No. 8 story* explained an FDA plan

to modernize its technology to adequately capture the large amounts of real-world evidence (RWE) that will flood the agency over the coming years, while *our No. 10 story* detailed concerns by the FDA's deputy director for regulatory affairs, Doug Stearn, that product recall notifications could be missed by stakeholders in a daily torrent of recall communications. And to add to the complexity around recalls, Stearn said the rise of so-called "big data" has greatly increased the agency's ability to detect and track safety issues.

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

Rank	Title
1	*FDA's Quality System Regulation Is Mapped To International Standard ISO 13485 – And Vice Versa – In New Report From AAMI*
2	*Three Candidates In Running To Become FDA Commissioner, Including Acting Chief Ned Sharpless*
3	*QSR/ISO 13485 Harmonization Update: FDA Enforcement Discretion Likely When New Rule Stands Up; Draft Reg Coming By Year's End*
4	*Wave Of Overhauled FDA 510(k) Guidance Documents Aims To Streamline Reviews*
5	*Industry, AJC Duke It Out In Georgia Over Ethylene Oxide Risk*
6	*FDA Finalizes Guidance On Benefit-Risk Uncertainty*
7	*It's Raining Guidance Docs: FDA Expands Abbreviated 510(k) Program*
8	*FDA Unveils Technology Modernization Plan To Better Handle 'Tsunami' Of Incoming RWE Data*
9	*AdvaMed Chair: Another Device Tax Moratorium More Likely Than A Full Repeal*
10	*'Big Data' Poses New Product Recall Challenges, FDA Official Says*