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US Regulatory Roundup, November 2019: EtO Woes Concern Industry; FDA Pushes Back Deadline For Blended QSR/ISO 13485 Rule; And More

by Shawn M. Schmitt

Concerns expressed by stakeholders during a two-day FDA meeting on the use of ethylene oxide (EtO) to sterilize medical devices was of most interest our online readers last month. EtO was also the focus of several other highly read stories – including worries by industry about device shortages and news that device maker Teleflex expects to lose millions because an EtO facility shut down. Meanwhile, the FDA's announcement that it would push back its deadline for delivering a draft version of a new rule that will harmonize its Quality System Regulation with ISO 13485 also garnered significant interest. Here are November's 10 most popular US regulation and policy stories from *Medtech Insight*.

Concerns expressed by stakeholders during a two-day US Food and Drug Administration meeting on the use of ethylene oxide (EtO) to sterilize medical devices was of most interest to *Medtech Insight*'s online readers in November.

That *No. 1 story* from last month reported on an array of EtO topics discussed at an early November meeting of the FDA's General Hospital and Personal Use Devices Panel. Several US states and their local environmental regulators are acting to reduce acceptable EtO emissions at plants that were at risk for shutting down temporarily or being banned from manufacturing EtO altogether.

Experts at the meeting said they want more data on the actual public-health risk from the use of EtO, cautioning that banning the sterilant could lead to even more harm due to device shortages

(which is what industry is worried about most, according to November's *No. 3 story*).

The FDA panel also reviewed recent deaths from duodenoscope infections, agreeing that the issue is less about the ability to sterilize available products and more about ensuring that technicians are properly trained and follow rigorous procedures when reprocessing them.

Speaking at the panel meeting, Phil Cogdill, director of quality sterilization and microbiology at Medtronic, stressed the importance of setting new EtO standards to clean devices. While it may take years for such standards to fully go into effect, he and other experts have already rolled up their sleeves to get the job done. Cogdill spoke with *Medtech Insight* in a podcast interview from the meeting in our *No. 4 story*.

And in our *No. 8 story* from November, specialty device maker Teleflex said it expects to lose $9m in the fourth quarter of 2019 due to the closure of a sterilization facility in Smyrna, GA, that uses EtO. The company said while it's looking for ways to mitigate the damage, it will likely lose even more money if the plant remains closed next year.

Quality And Compliance News

In other news of interest to *Medtech Insight* readers, the FDA announced that it would once again push back its deadline for delivering a draft version of a new rule that will harmonize its Quality System Regulation (QSR) with international standard ISO 13485. November's *No. 2 story* explained that the agency now plans to release its draft regulation in April 2020. But whenever the blended QSR/ISO 13485 rule is finally put in place, it will likely lead to a softer, gentler FDA inspectorate, an industry expert predicted in our *No. 6 story*.

The agency also announced last month that it will soon search for 10 manufacturers with problematic compliance histories to volunteer for a pilot program to improve the quality and maturity of their manufacturing organizations. Our reporting on that upcoming pilot was *No. 5* on our story list.

Launching in 2020, the pilot – colloquially known as the Noncompliant Site Voluntary Improvement Program (NSC VIP) – will be modeled on the agency's burgeoning *Case for Quality* Voluntary Improvement Program (CSQ VIP), which aims to elevate product, manufacturing and process quality at device firms by appraising the companies against an industry-modified version of the *Capability Maturity Model Integration* (CMMI) framework.

Other Popular November News

Other articles of interest to *Medtech Insight* readers last month: two US senators – Democrats Elizabeth Warren of Massachusetts and Patty Murray of Washington State – *sent a letter to FDA officials* that raises new concerns about the agency's legislative plan for a conditional progressive approval pathway for devices; President Trump *nominated MD Anderson Cancer Center oncologist*

Stephen Hahn to be the next FDA commissioner; and *Zimmer Biomet announced a high-risk class I recall* of its ROSA Brain 3.0 robotic surgery system.

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

Rank	Story
1	*US FDA Experts Caution Against Banning EtO, Encourage More Duodenoscope Training*
2	*Delayed Twice, FDA Now Says It Won't Release Its Harmonized QSR/ISO 13485 Draft Rule Until April 2020*
3	*Risk Of Sterilization Plant Shutdowns Across US Sends Shockwave Through Industry*
4	*Listen: Medtronic Exec Highlights Ethylene Oxide Standards At First Day Of FDA EtO Meeting*
5	*FDA's Case For Quality Head Explains The Agency's 2020 Maturity Model Pilot For Naughty Manufacturers*
6	*A Softer, Gentler FDA Inspectorate? It's Possible With QSR/ISO 13485 Harmonization, Auditing Expert Says*
7	*Senators Question FDA's Proposed Progressive Approval Pathway For Devices*
8	*Teleflex Says It Will Lose $9m – And Maybe More – Due To EtO Plant Shutdown*
9	*Trump Nominates Hahn As New FDA Commish; Acting Head Sharpless Returns To NCI*
10	*Software Issue Brings Recall Of Zimmer ROSA*