MEDTECH INSIGHT
CITELINE COMMERCIAL

06 Jun 2022 | **Analysis**

Expert: Granting More Than 1 Year To Comply With QMSR Rule Puts FDA In A Pickle

US Regulatory Roundup, May 2022

by Shawn M. Schmitt

Many commenters on the US FDA's draft Quality Management System Regulation want two or three years to comply, but one medtech expert says that length of time could put the agency in a difficult position. Our coverage of the FDA's draft QMSR – and an array of other news and analysis – topped our list of most-read *Medtech Insight* stories in May.

Could FDA Find Itself In A Harmonization Pickle?

How much time does the medtech industry need to comply with a final version of the US Food and Drug Administration's Quality Management System Regulation? Well, if you read many of the 69 comments to date from stakeholders on the draft QMSR, you'd think the answer is two to three years.

But the FDA's draft QMSR says one year is adequate. In fact, the director of the agency's Center for Devices and Radiological Health (CDRH), Jeff Shuren, said in *our No. 4 story from May* that the FDA "thought it was enough time" when it proposed what some consider a swift one-year transition from its current Quality System Regulation (QSR) to the new QMSR, when finalized.

In comments to the agency, though, top medtech *lobbying group AdvaMed* and the *American Society for Quality* say industry should be given three years for compliance. *So does Cook Medical*. Meanwhile, *Philips told the FDA* it wants two years.

Here's the rub: Granting more than a year for industry to transition could signal that the QMSR isn't as harmonized as the agency claims, says Dennis Gucciardo, a partner at the law firm

Morgan Lewis. After all, the draft QMSR is the result of a years-long harmonization effort by the FDA to combine the QSR with international quality systems standard ISO 13485:2016.

"You know, I've seen two, three years suggested," Gucciardo told *Medtech Insight*. "I think the hard part on that is, if FDA needs to make the case that ISO 13485 and the QSR are substantially similar, then why should they give companies a number of years to implement this rulemaking if they are, arguably, substantially similar? These are going to be interesting comments for FDA to respond to because the answer may cut against the agency's argument that [the standard and the QSR] are substantially similar, if the compliance timeline is something drastic" – e.g, two or three years.

Gucciardo is one of four medtech experts who sifted through stakeholder comments on the draft QMSR so *Medtech Insight* readers didn't have to. The expert takes from Gucciardo, Smith & Nephew's Vincent Cafiso, MEDIcept Inc.'s Kim Trautman, and King & Spalding's Steve Niedelman was our most-read story last month. You can read part one *here* and part two *here*.

Meanwhile, *our No. 6 story from May* explained how Philips and Hamilton Medical, in comments to the FDA, have asked the agency to address language in its proposed rule that the companies say would place onerous traceability requirements on most devices.

Expert Reviews Adverse Events Linked To Reusable Endoscopes

Medtech Insight readers were also highly interested in adverse events linked to reusable endoscopes; our story on the topic was *our third most-popular offering* last month.

A review of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, which houses all adverse events reported to the agency, found that events involving the endoscopes continued to rise between 2014 and 2021 despite increased attention to the risk of infection posed by the devices.

That's according to device safety specialist and consultant Larry Muscarella, who performed the MAUDE review. The president of LFM Healthcare Solutions examined more than 15,000 adverse event reports across six endoscope categories: bronchoscopes, colonoscopes, duodenoscopes, ear-nose-throat ("ENT") endoscopes, gastroscopes and urological endoscopes. He used 2014 as a baseline because it was when the FDA first publicly linked a duodenoscope to infections and death.

Muscarella's report found that the number of events involving endoscope contamination increased for each of the surveyed endoscope types. The largest increase was seen for gastroscopes, which rose from 13 reports in 2014 to 1,135 in 2021 – an increase of 8,630%. He further found that the number of reported events continued to increase even as the number of elective procedures being performed dropped in 2020 and 2021 because of the pandemic.

"That might tell you, even though we can't confirm it, that we may be seeing the tip of the iceberg and the problem really is worse than we understand," Muscarella said.

Philips Treads Troubled Waters

May was another difficult month for Philips Respironics as the company continued to grapple with its June 2021 recall of millions of breathing machines, including bi-level positive airway pressure (BiPAP), continuous positive airway pressure (CPAP), and other mechanical ventilator devices. The products were recalled because there's a risk that users could inhale degraded sound abatement foam.

The month started off with the FDA publicly explaining that it's considering issuing an order to force Philips to repair or replace recalled devices, or issue recalls to their purchasers. To date the agency has not said whether it will follow through with such an order, which would be carried out under Sec. 518(b) of the Food, Drug, and Cosmetic Act. That gives the agency the authority to force "manufacturers, importers or distributors to repair, replace or refund the purchase price of devices that present unreasonable health risks."

The order, if put in place, would apply to recalled devices made after November 2015. Our reporting on the FDA's latest move against Philips was *our No. 5 story from May*.

A few weeks later, on 19 May, *the FDA said it received more than 21,000 Medical Device Reports* between April 2021 and April 2022 related to the recalled devices. The MDRs included 124 reports of death, the agency said, and "included both mandatory reports from Philips and voluntary reports from health professionals, consumers and patients."

The FDA further said a "wide range of injuries" were found in the MDRs, "including cancer, pneumonia, asthma, other respiratory problems, infection, headache, cough, dyspnea (difficulty breathing), dizziness, nodules and chest pain."

Other Top Stories

These five articles rounded out our Top 10 list in May:

- *No. 2 story*: CDRH director Shuren warns of "critical regulatory hurdles" if Congress doesn't soon update reg frameworks for digital health products.

- *No. 7 story*: Draft legislation out of the Senate Health, Education, Labor and Pensions (HELP) Committee gives the FDA authority to regulate certain *in vitro* diagnostics known as lab-developed tests.

- *No. 8 story*: The FDA is weighing whether new regulatory pathways are needed for certain types of human cells, tissues, and cellular and tissue-based products (HCT/Ps).

- *No. 9 story*: A draft guidance document was issued by the FDA to officially recognize the Case for Quality Voluntary Improvement Program. CfQ VIP aims to advance quality in devices and their manufacturing.

- *No. 10 story*: CDRH director Shuren explains why the FDA in early May split its Office of In Vitro Diagnostics and Radiological Health in two.

The 10 most popular US regulation and policy stories in May, as determined by reader interest, are listed in the table below.

Rank	Story
1	*FDA's QMSR: 3 Experts Read Draft Rule Comments So You Don't Have To. Here's What They Saw*
2	*Digital Health: FDA's Shuren Predicts 'Critical Regulatory Hurdles' If Congress Doesn't Update Reg Frameworks*
3	*Study: FDA Data Shows Endoscope-Related Adverse Events Continue To Rise*
4	*'If You Know The Answer, Let Me Know': FDA's Shuren Mum On 1 Year Transition For Coming QMSR Reg*
5	*Escalation: FDA Wants Philips To Repair, Replace Or Give Refunds For Recalled Breathing Machines*
6	*Philips, Hamilton Medical To FDA: QMSR Shouldn't Subject Devices To ISO Traceability Requirements*
7	*Senate Bill Establishes Greater Regulatory Oversight Of Lab Developed Tests*
8	*FDA Considers New Regulatory Pathways For Some Cellular Products*
9	*FDA Draft Guidance Would Set In Stone Case For Quality Voluntary Improvement Program*
10	*FDA's Shuren On Why Agency Broke Up Its IVD And Radiological Health Office*