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US Regulatory Roundup, May 2021: FDA, FDA, And Even More FDA

by Shawn M. Schmitt

From regulation to recalls, breakthrough devices to the Case for Quality, news from the US agency came in hot and heavy last month. Check out our list of most-read *Medtech Insight* articles from May.

FDA News Reigns Supreme

From regulation to recalls, breakthrough devices to the Case for Quality, a boatload of medtech-related news came out of the US Food and Drug Administration last month. Here's a roundup of the most talked-about *Medtech Insight* stories from May, as determined by reader interest.

QSR: 'Full-Steam Ahead'

In our No. 1 story from last month, the director of the FDA's device center, Jeff Shuren, assured device makers that the agency's efforts around harmonizing its Quality System Regulation with ISO 13485 are "back on track." The FDA has been harmonizing its QSR with the international quality systems standard since 2018.

Because of the coronavirus pandemic, "priorities like the regulation on formally adopting and transitioning to the ISO 13485 standard from our QSR … [was] taking longer. I will tell you, [that effort] is back on track. [It's] moving forward and we're making great progress, and trying to get back to normal," Shuren said at MedCon 2021, hosted by the agency and Cincinnati's Xavier University.

He also defended the amount of time the agency has taken to craft the draft rule: "We want to make sure we do it right and have done the right crosswalk … [between] the QSR and the standard. And secondly, we got hit by COVID … so things took a little bit longer. But … we're back on track. It's full-steam ahead with that proposed regulation."

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Inspections Report & Inspectional Affairs Council

The FDA said in an early May report that its best-case scenario would involve conducting only half of its planned domestic surveillance inspections this fiscal year, which ends on 30 September.

Our No. 6 story explained that the agency still has 3,229 surveillance inspections to carry out in FY 2021 of manufacturers of human and animal medical products, as well as tobacco products. But because of the coronavirus pandemic, the FDA says under the best conditions it will likely perform only 1,613 of those inspections, or 50% of what it had planned.

Of those 3,229 inspections, 2,002 are earmarked for medical device companies and firms that make non-medtech products also overseen by the agency's Center for Devices and Radiological Health (CDRH). Inspections related to the Mammography Quality Standards Act are also lumped in with that figure; MQSA inspections – mandated annually by law – make up roughly 800 of the FDA's 2,002 planned inspections.

In *follow-up news* from 28 May, the FDA predicted in its FY 2022 budget request that it will likely inspect only 75 device manufacturers by the end of FY 2021. But in a strong signal that the agency believes it'll be ready to send its inspectorate back into the field beginning this October, it estimated that it will conduct 1,400 inspections of firms in FY '22.

Also in inspections news, the FDA announced last month the creation of an Inspectional Affairs Council. *Our reporting on that* was also of high interest to readers last month.

The FDA's announcement was notably anemic, however, saying it was "establishing an agency-wide FDA Inspectional Affairs Council that will plan and coordinate inspectional activities," but giving no specifics. The agency's Office of Regulatory Affairs – which conducts all of the FDA's field activities – already plans and coordinates inspections, so it's unclear exactly how the new council would complement those efforts.

When asked at MedCon about the new council, Jeff Shuren would only say that "it's anticipated we will have senior-level folks from across the agency participating."

Update On Case For Quality Programs

Our No. 5 story from May highlighted FDA data that show device companies taking part in a pilot program to streamline the corrective and preventive action process closed 74% of open CAPAs within a brisk 90 days.

Under the umbrella of the joint FDA/Medical Device Innovation Consortium (MDIC) Case for

Quality collaborative community (CfQcc), the CAPA Process Pilot shifts corrective and preventive action from a one-size-fits-all method to a more nuanced approach that separates higher-risk events from others that don't need to be elevated to the level of a traditional CAPA. The goal is to help firms focus on the most important events that could impact product quality and patient experience, rather than dumping every event into their CAPA system.

For its numbers, the FDA compared "pilot CAPAs" to "baseline CAPAs" that were outside the pilot program. Of 160 pilot CAPAs reviewed, 119 (74%) were closed within three months. Of those, 98 (61%) were closed in fewer than 60 days. Meanwhile, a majority of the 201 baseline CAPAs reviewed by the agency – 59%, or 119 – took more than 180 days to close, an FDA official said at MedCon.

Meanwhile, agency officials said last month that another Case for Quality program run by the FDA and MDIC – the Case for Quality Voluntary Improvement Program (CfQ VIP) – has sparked a culture shift at the agency.

CfQ VIP 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. Companies enrolled in CfQ VIP receive a bevy of benefits from the FDA, including streamlined and accelerated options for 30-day notices, site-transfer changes and premarket submissions. The agency offers the incentives because successful participation in the program gives FDA product reviewers a level of quality assurance.

"The organizations that have been engaged with us up until now have been … transparent. We've seen shifts in the way the [FDA] review teams and the review divisions interact with the organizations, [and] the level of information that's shared," said Cisco Vicenty, CfQcc program manager in the CDRH's Office of Product Evaluation and Quality (OPEQ).

That interaction between regulator and regulatee, he says, has led to a "broader culture shift" at the FDA. That shift is "starting to … feed and percolate into other areas and other activities that the center's been engaged in. New initiatives that [the CDRH is] looking at and considering moving forward with that are intended to be more collaborative to solve the problem – tackling things like building out supplier resilience and managing [product] shortages earlier ahead of time," Vicenty said at MedCon.

Pointers For Makers Of Breakthrough Devices

Device makers looking to get a product cleared through the FDA's breakthrough devices pathway must work closely with the agency during the 60-day review "sprint." So says Owen Faris, principal deputy director of the OPEQ.

Faris acknowledged at MedCon that the breakthrough timeline as laid out in statute and followed by FDA review teams is tight. "We get the request on day zero, then spend the first 30 days conducting a substantive review. At the end of that 30 days, we're deciding whether to grant or deny the clearance, or request additional information and pause the review," he said. "When we ask questions of a firm, we expect them to turn it around quickly so we can keep within the 60 days. So when you send a [breakthrough] submission in, please expect and be ready for questions. It can help avoid surprises further down the road."

Check out more breakthrough pathway tips from the FDA's Faris *here*.

Keeping Tabs On Class II Recalls

Manufacturers are being warned by the FDA that it's keeping a sharp eye on firms that initiate moderate-risk class II recalls – especially those that trigger multiple class II's in a given year. That's the upshot from our *No. 8 story* from May.

An analysis of fiscal year 2020 class II recalls by the agency found that more than 30 device makers had at least three class II's during that time frame, from October 2019 to September 2020. Overall, the FDA looked at 437 class II recalls for its review.

"We are really starting to look closely and more in-depth at class II recalls," Meredith Andress, recall coordinator for Div. 2 of the FDA's Office of Medical Device and Radiological Health Operations, said at MedCon. "And when we see multiple recalls for one firm, it can signal concern on our end at FDA."

Meanwhile, our *No. 9 story* reported that recalls initiated by industry were relatively stable in the first quarter of 2021 as companies recalled 212 products, a 10% decrease from the previous quarter.

Other Top Stories

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

No. 2 story: In a move that undoubtedly ruffled industry feathers, the Centers for Medicare and Medicaid Services issued a final rule that punts implementation of the Medicare Coverage of Innovative Technology (MCIT) breakthrough devices regulation to mid-December.

No. 4 story: Quality and regulatory experts from Boston Scientific, Becton Dickinson and Steris offered tips on supporting the mental health of employees, virtually onboarding new hires, and more in the age of COVID-19.

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	*After QSR Delays, 'It's Full-Steam Ahead With That Proposed Regulation,' FDA's Shuren Vows*
2	*CMS Kicks Can Down Road By Pushing MCIT Breakthrough Devices Rule To Dec. 15. Here's Why*
3	*FDA's Shuren: 'Senior-Level Folks' Will Take Part In New Inspectional Affairs Council*
4	*Q&A: Boston Scientific, BD, Steris Tell How They're Backing Up Their Workers In 'The New Normal'*
5	*Device Makers In Joint FDA/MDIC Pilot Closing CAPAs Faster, Agency Reports*
6	*At Best, FDA Will Carry Out Only Half Of Domestic Surveillance Inspections In FY 2021, Report Says*
7	*Sprinting To Approval: Insider Tips On FDA's Breakthrough Devices Program*
8	*FDA Warns Industry: We're Looking 'Closely And More In-Depth At Class II Recalls'*
9	*Q1 Recalls Snapshot: It's A Mixed Bag As Device Recalls Fall 10% But Recalled Units Rise 3%*
10	*Success Of Case For Quality Program Triggers 'Culture Shift' At FDA's Device Center, Officials Say*