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US Regulatory Roundup, February 2021: QA/RA Predictions, FDA Warning Letter Stats, PMA Case Study, And More

by Shawn M. Schmitt

Quality and regulatory predictions for 2021, a count of 2020 US FDA enforcement missives, a premarket approval case study for a novel prosthetic, and more topped our list of most-read *Medtech Insight* articles in February.

Quality And Regulatory Predictions For 2021

Earlier this year, industry expert Eric Henry predicted that the US Food and Drug Administration wouldn't publish a draft of its retooled Quality System Regulation by the end of February.

"It would surprise me if the FDA released [the draft rule] in February," Henry – senior quality & regulatory compliance advisor at the law firm King & Spalding – told *Medtech Insight* in January. "But that's just my opinion."

As it turns out, he was right. The agency missed its latest internal deadline for publishing the draft QSR, which the agency has been harmonizing with international quality systems standard ISO 13485:2016 since 2018. The FDA's February 2021 target date *was the fifth it failed to meet*.

And that wasn't the only prediction Henry made. *In our No. 1 story* from last month, he also said device makers should prepare for "hybrid" facility inspections because of the coronavirus pandemic: "I do expect that the FDA will leverage remote tools in combination with on-site visits as a hybrid way of addressing things – especially for your first product submissions. I'm assuming it will be toward the end of the last half of this year before they would go back on-site at all, and the volume may not hit normal pace until next year."

The FDA has been trying out different remote assessment tools, including *records requests* and the *use of video*. It's also putting together a *pilot program for remote inspections*. Once the agency

charts the best path forward for conducting remote inspections, companies can expect an increase in enforcement to follow.

"With this hybrid approach, industry is going to see an uptick in FDA-483s [inspectional observation forms] and non-COVID-related warning letters," Henry said.

Quality-Related Warning Letters Remained Steady In 2020

Speaking of warning letters *not* related to COVID-19: The FDA sent 21 quality-related enforcement missives to manufacturers in 2020, data from the agency show. That's the same number of letters that firms received in 2019.

The FDA considers quality-related warning letters to be those that include an alleged violation of its Quality System Regulation. In its count, the agency did not include letters that solely pertain to the Medical Device Reporting (MDR) regulation (21 CFR, Part 803), the Corrections and Removals regulation (21 CFR, Part 806), or premarket activities.

In our No. 4 story from February, we explained that of the 21 warning letters issued last year, 12 were sent to US companies and nine went to firms based outside the US. The count represents a massive 83% drop from just five years before, when the agency mailed out 121 of the letters.

Nevertheless, FDA spokesperson Audra Harrison told *Medtech Insight* that warning letters are "one of several tools we use to ensure … compliance," and the number of letters sent to firms "should not be used to broadly assess industry compliance with QSR requirements or the agency's actions to ensure the same."

CDRH's Shuren: Pressure Mounts On FDA Reviewers

In other FDA news, Center for Devices and Radiological Health (CDRH) director Jeff Shuren said in an interview with *Medtech Insight* that the pandemic has taken a toll on the agency's ability to review premarket applications.

Shuren said in *February's No. 3 story* that the FDA has stretched its resources to the limit and as a result, some applications are taking much longer than expected. He also acknowledged that reviewers are feeling squeezed. The agency to date has received more than 2,000 pre-emergency use authorizations and another 3,000 EUAs, while also accepting roughly the same number of traditional product submissions.

There was "a tremendous increase in workload [but] the number of people in the center did not double," Shuren said. "As a result, we have had to temporarily reassign staff to support our COVID-19 efforts, delayed the review of an increasing number of non-COVID submissions, deny requests for pre-submission meetings and delay other priority work, including important congressionally mandated deliverables, such as the over-the-counter hearing-aid rule and the

remanufacturing guidance."

And *our No. 7 story* from February explained how FDA resources made scarce by the pandemic, as well as key staff leaving the CDRH, likely contributed to a delayed artificial intelligence and machine learning (AI/ML) medical software action plan that was published by the agency in January.

Case Study: How Integrum Won A PMA For OPRA

Our in-depth feature on Swedish start-up Integrum's unconventional route to premarket approval for a novel prosthetic also garnered strong reader interest last month.

The Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA) Implant System is intended for use by adults with above-the-knee amputations who cannot use, or who are anticipated to have problems with, a conventional socket prosthesis.

Integrum worked with a team at the law firm Hogan Lovells to secure its PMA. A partner at the firm, Jonathan Kahan, told *Medtech Insight* that he wasn't sure that the FDA would ultimately approve the device. He said gaining approval wasn't "necessarily a slam dunk," noting that it was a "difficult project" to work on.

That's because decades' worth of data on OPRA, a lot of it located outside the US, had to be rounded up in support of the prosthetic's PMA. Kahan said device makers typically don't go to the FDA for approval with existing data that they already have and tailor it to what the agency is requiring. But that's exactly what Integrum and Hogan Lovells did.

Read our case study on OPRA *here*, and listen to our *Device Week* podcast on the topic below:

Click here to explore this interactive content online

Recalls, Recalls, And More Recalls

Last month there was a plethora of recalls news tied to products made by high-profile device manufacturers, including *Medtronic*, *Boston Scientific* and *Smiths Medical*.

Meanwhile, our *most recent recalls infographic* showed that the number of corrections and removals fell slightly in the fourth quarter of 2020 – but there was an increase in the count of recalled device units.

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

Rank	Story
1	QA/RA Outlook 2021: 4 Hotspots To Watch, From 'Hybrid' US FDA Inspections To QSR Harmonization
2	Securing FDA Approval For Novel OPRA Prosthetic Wasn't A 'Slam Dunk.' Here's How Start-Up Integrum Made It Through The PMA Maze
3	FDA's Shuren: Staff Overburdened, Review Times Seeing Negative Effects
4	FDA Inspections All But Stopped In 2020 – But Quality-Related Warning Letters Kept On Coming
5	Recall Of Valiant Navion Could Cost Medtronic $40M
6	Death, Serious Injuries Lead To Class I Recall For Boston Scientific's Emblem Electrode
7	Experts: COVID-19, Departure Of Key FDA Staff Likely Contributing Factors For Delayed AI/ML Action Plan
8	Déjà Vu: Boston Scientific's Emblem Racks Up Another Class I Recall This Month
9	Class I Recall For Smiths Medical's Medfusion Syringe Pumps
10	Q4 Recalls Snapshot: Fewer Devices Recalled By Industry, But Software Troubles Still Abound