MEDTECH INSIGHT
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QSR Author Says FDA – Not Industry – Will Need Most Time To Adapt To New Quality System Reg

US Regulatory Roundup, August 2021

by Shawn M. Schmitt

Predictions made by Kim Trautman, lead author of the US FDA's Quality System Regulation, and four other top medtech experts regarding the agency's upcoming harmonized QSR topped our list of most-read *Medtech Insight* articles in August.

It's All About Quality

The lead author of the US Food and Drug Administration's Quality System Regulation predicts that device makers won't need as much time as the agency to adapt to a new QSR that's harmonized with international quality systems standard ISO 13485:2016.

"Under the assumption that FDA is successful in their intended purpose of further harmonizing [the Quality System Regulation] to match 13485, then industry should need little time to transition," said Kim Trautman, who worked on the current QSR in the 1990s when she was the agency's quality systems expert for medtech. That's because, she says, most firms already follow the ISO standard to gain market access in countries outside the US.

Instead, she believes "the transition time needed will be greater within FDA. There are literally so many documents that have to be updated, even if it's just tweaking guidances to have certain references, et cetera, et cetera."

Trautman – a longtime device, IVD and combination product expert – is one of five industry insiders that *Medtech Insight* rounded up to talk about the upcoming harmonized draft QSR. *This insightful "man on the street" feature* was our most popular story in August.

She further noted that the FDA's "compliance program will have to be reviewed and possibly revised, depending on the changes. ...In addition to the training and rolling out in a consistent manner to this whole inspectorate, the new requirements, that's where there's going to be more time needed and training needed, and it's going to be on the FDA side more than on the industry side."

The FDA has been harmonizing its QSR – the bedrock regulation for manufacturing safe and effective devices in the US – with ISO 13485 for more than three years. A draft of the new rule is expected by the end of the year.

> ***"Quality and safety are first, and then everything else follows." – Medha Trivedi***

And in our *No. 3 story* from last month, experts at device giants *Stryker Corp.* and *Baxter Healthcare* explained that manufacturers that foster a culture of quality throughout their organizations and prioritize quality over compliance can reap a bevy of benefits, including initiating fewer recalls and getting product to market quicker.

"At Stryker we have been on the quality-first journey for a very long time now, and it's essentially around the top, from the tone we hear from our CEO onwards, and all business leaders. Quality is first in everything we do," said Medha Trivedi, the company's senior director of global quality & operations.

She pointed out that quality is discussed amongst Stryker's manufacturing teams and emphasized during daily meetings, and the quality-first concept is also a regular topic during business-review meetings. "We focus a lot on the quality-first mentality. And in terms of the prioritization, quality is always first," Trivedi said. "Quality and safety are first, and then everything else follows."

Recalls Front And Center

Product recalls news was also of high interest to *Medtech Insight* readers in August.

In our *No. 2 story*, Democratic Sen. Richard Blumenthal sent a letter to *Philips North America* CEO Vitor Rocha that demanded answers regarding a high-risk class I recall of more than 2 million bi-level positive airway pressure (BiPAP), continuous positive airway pressure (CPAP), and other mechanical ventilator devices.

The company recalled the products in June because the sound abatement foam inside the units can break down over time, posing a risk to patients.

The Connecticut lawmaker said in his 24 August letter that the company hasn't been adequately transparent about the recall with patients and other stakeholders. "I am so alarmed that even after several months, too many patients have yet to receive the promised repair kits and replacements … and many patients may not even know of the recalled status of their device," Blumenthal wrote. "For these patients, Philips has presented a false choice of foregoing essential, sometimes lifesaving care, or using a defective product that could itself result in death."

Rocha has until 7 September to answer seven questions asked by the senator in his letter. Meanwhile, the CEO of *Royal Philips*, Frans van Houten, said on 1 September that it will take the company *a full year to fix or replace the recalled devices*.

In other recall-related news, the FDA sent a *warning letter* to China-based Lepu Medical Technologies roughly two months after the agency told health care providers and other stakeholders to stop using COVID-19 diagnostics made by the firm. Our *No. 5 story* reported that the FDA's enforcement missive accused Lepu Medical of selling the Neutralization Antibody Test Kit, SARS-CoV-2 Antigen Rapid Test Kit, and Saliva Antigen Rapid Test without agency clearance, approval or authorization.

The warning letter followed a recall by the company of its SARS-CoV-2 Antigen Rapid Test Kit and Leccurate SARS-CoV-2 Antibody Rapid Test Kit. The recall was initiated by the firm in April and was designated as high-risk class I by the FDA in May.

And in our *No. 6 story*, two deaths were linked to missing instructions for use (IFU) for a *Cardinal Health Inc.* scalpel used during childbirth. The Safety Scalpel N11 is part of the company's Argyle UVC Insertion Tray, which was recalled in June due to the missing IFU.

Because the scalpel's IFU isn't included with the recalled trays, health care providers could have problems with the scalpel's permanent locking feature, said the FDA, which gave the recall a high-risk class I designation. A "clinician's inability to use the scalpel (when in the permanent locked position) poses a safety risk to the patient that could result in delayed treatment, which could lead to serious injury or death," the agency said.

'Intended Use' Rule Now In Effect

In a final rule released in early August, the FDA broadened the benchmarks for what can be considered evidence for intended use of a device or drug. The new rule, which went into effect on 1 September, remained largely unchanged from its draft version. Our reporting on this took the No. 4 spot on August's most-read list.

Under the rule the FDA's view is that a device maker's mere knowledge about a product's off-label use does not necessarily mean that the manufacturer intended it for such use. And while that might seem to shield a company from liability for the unintended use of its product by someone else, it also gives the agency more leeway in making a case against a manufacturer for an off-label violation.

Read our story on the rule *here* or listen to our *Device Week podcast* on the topic below.

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Other Top Stories

These four articles rounded out our Top 10 list in August:

- *No. 7 story*: In this opinion piece, former FDA device center compliance chief Steve Silverman argues that the agency and stakeholders should take steps now to develop a remote-inspection framework for device makers.

- *No. 8 story*: The FDA says it yanked accreditation for third-party reviewer Accelerated Device Approval Services because it lied to a sponsor about a nonexistent reviewer and its communications with regulators.

- *No. 9 story*: A proposed change to Medicare billing that would go into effect on 1 January could give one maker of implantable stents for glaucoma an edge over its competitor.

- *No. 10 story*: The FDA won't contest a recent court decision that concluded radiology contrast agents should be treated as devices and not drugs. As a result, the agency will begin treating a slew of such products as devices.

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

Rank	Story
1	*QSR Q&A: 5 Top Medtech Experts Answer 6 Burning Questions About FDA's Coming Quality Reg Redo*
2	*Senator To Philips CEO: Fork Over Info On Class I Recall Of Sleep, Ventilator Devices – Pronto*
3	*Device Giants Stryker And Baxter Embrace A 'Quality First' Culture – And Yield Positive Results*
4	*FDA Widens Scope In Considering Evidence For Off-Label Use*
5	*Double Whammy: Lepu Medical's Class I COVID-19 Diagnostics Recall Followed By FDA*

	Warning Letter
6	*2 Deaths Linked To Missing IFU For Cardinal Health Scalpel Used For Newborns*
7	*Come On In, The Water's Fine: FDA Should Fully Embrace Remote Inspections*
8	*FDA Blacklists Third-Party Reviewer For Lying To Sponsors, Agency*
9	*Proposed Medicare Code Change Could Affect Reimbursements On Glaucoma Devices*
10	*Imaging Drugs Make Jump To Devices In New Decision By FDA*