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After 3 Years Of Work, FDA Says It Will Release Its Revamped Quality System Regulation This Month

by Shawn M. Schmitt

The US FDA's updated regulatory agenda says the agency will release a draft of its revised QSR in June 2021. But industry has seen this song and dance before – so will the FDA finally deliver the goods this time?

After three long years of waiting, could this be the month the US Food and Drug Administration finally releases a draft of its revamped Quality System Regulation?

The FDA seems to think so; *it updated its official regulatory agenda* to note that the draft will come in June 2021. The agency has been harmonizing its QSR with international quality systems standard ISO 13485:2016 since early 2018.

But much like Lucy with the football, the FDA has a knack of setting a release date for the draft QSR, only to blow past it. That's happened five times since 2019, with the latest deadline missed being February of this year. (Also see "*FDA Misses Fifth Target Date For Issuing Draft Harmonized Quality System Reg*" - Medtech Insight, 1 Mar, 2021.)

So it's impossible to know if the agency actually will deliver the goods this month. But FDA device center officials, including director Jeff Shuren, have said recently that the updated QSR will come in 2021 – no ifs, ands, or buts.

> ***After QSR Delays, 'It's Full-Steam Ahead With That Proposed Regulation,' FDA's Shuren Vows***
>
> By Shawn M. Schmitt
>
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Shuren said in early May that despite hurdles and setbacks at the FDA, including tackling the COVID-19 pandemic, QSR harmonization activities were "back on track."

(*See sidebar story.*)

"It's full-steam ahead with that proposed regulation," he said at MedCon 2021, hosted by the FDA and Cincinnati's Xavier University. "I don't have a crystal ball on timing, simply because a lot of it's out of our hands, but our goal is it will happen this year. It's a top priority for us, and from our perspective, sooner is a heck of a lot better than later."

Jeff Shuren, director of the US FDA's Center for Devices and Radiological Health, said on 6 May that the agency's efforts around harmonizing its Quality System Regulation with ISO 13485 are "back on track."

Read the full article here

The FDA's QSR has been the bedrock rule for manufacturing safe and effective medical devices to be sold in the US for more than two decades, while ISO 13485 is used by device firms to ensure quality systems compliance with regulators in a variety of countries.