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OMB Completes Review Of FDA's Draft Harmonized Quality System Regulation

by Shawn M. Schmitt

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The White House Office of Management and Budget (OMB) on 8 February *completed its regulatory review* of the US Food and Drug Administration's draft harmonized Quality System Regulation.

The OMB finished its review in a swift 35 days. The FDA had sent the draft rule to the office on 5 January after working on it for nearly four years. (Also see "*At Long Last, FDA Sends Draft Harmonized Quality System Regulation To OMB For Review*" - Medtech Insight, 7 Jan, 2022.)

The OMB's concluded action was "consistent with change," which means modifications were made to the draft reg during its review. However, the "consistent with change" code doesn't differentiate between small editorial tweaks and modifications that drastically alter a rule, so it's difficult to discern if the changes were minor or if the FDA has to go back to the drawing board, let alone how long it might be before the draft is available to the public.

Too Slow, Too Fast, Or Just Right? Experts Weigh In On OMB's 35-Day Review Of FDA's Draft QSR

By Shawn M. Schmitt

11 Feb 2022
Did the White House Office of Management and Budget review the US FDA's draft harmonized Quality System Regulation too quickly to be thorough? Some industry experts say yes, while others are more optimistic.

Read the full article here

The agency has been harmonizing its Quality System Regulation with international quality systems standard ISO 13485:2016 since early 2018. The QSR has been the bedrock rule for manufacturing safe and

effective medical devices to be sold in the US since the mid-1990s, while ISO 13485 is used by device firms to ensure quality systems compliance with regulators in a variety of countries.