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FDA Picks New Target Date For Releasing Its Draft Harmonized Quality System Regulation

by Shawn M. Schmitt

February 2021 is the latest target date selected by the US agency for releasing a draft of its retooled QSR, which has been undergoing a facelift for more than two years to harmonize it with international quality systems standard ISO 13485.

The US Food and Drug Administration has selected *February 2021* as the latest target date for releasing a draft of its retooled Quality System Regulation, which has been undergoing a facelift since early 2018.

This is the fifth in-house deadline the FDA has set for issuing its draft rule, which will harmonize the QSR with international quality systems standard ISO 13485:2016. The agency had previously set deadlines of *April 2019*, *September 2019*, *April 2020* and *October 2020*.

The QSR is the bedrock rule for manufacturing safe and effective medical devices to be sold in the US, while ISO 13485 is used by manufacturers to ensure quality systems compliance with regulators in a variety of countries, including Canada, Japan, Australia, the UK and the 27 member states of the EU.

Elizabeth Miller, assistant commissioner of medical products and tobacco operations within the FDA's Office of Regulatory Affairs, confirmed last month that the draft rule would come in 2021. (Also see "*FDA Official Confirms 2021 For Release Of Draft QSR, Asks For 'Inclusive Comment Spectrum'*" - Medtech Insight, 17 Nov, 2020.)

She said the agency is looking forward to receiving an "inclusive comment spectrum" from stakeholders after the draft reg is published in the Federal Register.