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FDA delays draft rule for QSR/ISO 13485 harmonization

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The U.S. Food and Drug Administration (FDA) indicated that the long-anticipated proposed rule modernizing the Quality System Regulation (QSR) is now targeted for release in April 2020. This is the second delay in the agency's efforts to harmonize the framework regulating quality systems with the international consensus standard for medical device manufacture, ISO 13485:2016.

The new April 2020 projected publication date was announced in the recently updated regulatory agenda. The draft rule, initially announced in May 2018 for publication in April 2019, was first postponed to September 2019. We understand that the serial delays in releasing the proposed harmonized regulatory framework are a reflection of the agency's ongoing internal challenges with development of the proposed rule.

The rule is intended to reduce compliance burdens on U.S. manufacturers by harmonizing domestic and international standards. The revisions will also modernize the regulation.

Industry and its stakeholders are interested in determining the nature and scope of the changes planned by FDA. It is still to be determined as to whether the changes will reflect a wholesale rewrite of the QSR to better reflect ISO 13485:2016 or modifications to certain portions of the QSR to better align with ISO 13485:2016 (e.g., explicitly introducing risk management in certain quality subsystems).

Contacts

Edward C. Wilson, Jr.
Partner, Washington, D.C.
T +1 202 637 5839
ted.wilson@hoganlovells.com

Michael S. Heyl
Partner, Washington, D.C.
T +1 202 637 5456
mike.heyl@hoganlovells.com

Jodi Scott
Partner, Denver
T +1 303 454 2463
jodi.scott@hoganlovells.com

Dennis C. Gucciardo
Counsel, Washington, D.C.
T +1 202 637 3590
dennis.gucciardo@hoganlovells.com