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ALERTS

FDA Proposes To Harmonize Medical Device Quality System Regulations With ISO 13485

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Highlights

The FDA has published a proposed rule to align its medical device quality system regulations with the ISO 13485 quality system

The rule should make compliance more efficient

Comments on the proposed rule are due on May 24, 2022

The Food and Drug Administration (FDA) published a proposed rule in the Federal Register "proposing to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) Regulation to align more closely with… the 2016 edition of ISO 13485."

While mainly procedural, the goal of the rule is to make compliance easier and more efficient, and to avoid creating inconsistencies with other applicable FDA requirements. Some industry participants who manufacture medical devices have already expressed concern with the proposed effective date of one year after the rule is finalized.

Comments on the proposed rule, which was introduced in February, are due May 24, 2022.

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With the proposed rule, the FDA intends to amend 21 C.F.R. Part 820 and other sections by incorporating reference to the quality management system requirements of the International Organization for Standardization known as ISO 13485. As a result, the FDA's quality regulations will be harmonized with many others throughout the world and better facilitate compliance.

However, the FDA does propose to retain the scope of its current regulation and to retain and modify a number of the definitions in the current Part 820. The additions will ensure that the incorporation by reference of ISO 13485 does not create inconsistencies with other applicable FDA requirements. The result will be referred to as the Quality Management System Regulation (QMSR).

The FDA is also proposing conforming edits to 21 C.F.R. Part 4 to clarify the device QMS requirements for combination products. These edits would not affect the CGMP requirements for combination products.

According to the FDA, if finalized, the rule will converge quality system regulation with the QMS requirements of ISO 13485 while continuing to provide the same level of assurance of safety and effectiveness under the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

For more information, please contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler, chair of the firm's Food, Drug and Device group, at 317-231-7392 or lynn.tyler@btlaw.com.