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FDA Seek Comments on Quality System (QS) Regulation Amendments

By **IVT Staff Mar 1, 2022 8:00 am EST**

Late last month after much hard work and deliberation the FDA released a draft rule harmonizing the Quality System Regulation – 21 CFR, Part 820 (QSR) with ISO 13485:2016. The revisions are intended to reduce compliance and recordkeeping burdens on device manufacturers, by more closely aligning domestic quality system requirements and international standards. The revisions will also modernize the current regulations.

The QSR has been the guidepost for the safe and effective manufacturing of medical devices sold in the US since the mid-1990s, while ISO 13485 has been the leading Quality Systems Compliance standard with regulatory agencies across the globe.

According to the FDA website, “The most noticeable difference between the QS regulation and the standard is the risk management requirements integrated throughout the aspects of the quality management system in ISO 13485. This differs from 21 CFR 820, in that the only risk-specific requirement in the QS regulation is listed in §820.30(g), as it relates to risk analysis as a part of design validation.”

Other changes expected include signature and date requirements for records and reporting requirements for complaints and service-related activities. The agency also plans to keep its current stipulations for device labeling and packaging since the international standard does not specifically address the inspection of labeling by manufacturers.

Electronic or written comments on the proposed rule must be submitted by May 24, 2022. Electronic comments must be submitted via https://www.regulations.gov. Written submissions may be submitted to: Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Tomorrow the Device Good Manufacturing Practice Advisory Committee while convene to "discuss and make recommendations on the current good manufacturing practice requirements for medical devices under 21 CFR part 820 ... to align more closely with an international consensus standard for medical devices used by other regulatory authorities."

You may review the Medical Devices; Quality System Regulation Amendments here. If you have questions about this proposed rule, send an email to Proposed-Device-QMSR-Rule@fda.hhs.gov.

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