

FDA Final Rule: Medical Device Quality System Regulation Amendments

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For many years the rest of the world has been utilising the ISO 13485 Medical Device Quality Management System standard as a means for companies to show compliance to regulatory requirements and to ensure safe and effective products are placed on the market.

The US FDA is now revising its medical device Current Good Manufacturing Practices (CGMP) requirements as set forth in the QSR, codified in part 820 (21 CFR part 820). FDA is accomplishing this primarily by incorporating by reference the 2016 edition of ISO 13485. Through this rulemaking, FDA is harmonizing quality management system requirements for medical devices with requirements used by other regulatory authorities.

This rule was published late January 2024¹ and is **effective February 2, 2026**.

The title of the regulation is being amended and there are additional requirements and provisions that clarify certain expectations and certain concepts used in ISO 13485. This revised part 820 is referred to as the **Quality Management System Regulation (QMSR)**.

There are some significant changes that manufacturers with sales outside the USA will probably be well placed to address, but those with only domestic US sales may need to upgrade somewhat. The changes primarily affect the following areas:

Documenting the quality management system that complies with the applicable requirements of ISO 13485, as incorporated by reference in § 820.7, and other applicable requirements of part 820.

Complying with the requirements in ***Design and Development***, Clause 7.3, and its subclauses in ISO 13485.

Under § 820.10(d), manufacturers of devices that support or sustain life, the failure of which to perform properly can be reasonably expected to result in a significant injury, must comply with the requirements in ***Traceability for Implantable Devices***, Clause 7.5.9.2 in ISO 13485.

Control of records (§ 820.35). In addition to the requirements of Clause 4.2.5 in ISO 13485, Control of Records, the manufacturer must maintain certain records as provided for in § 820.35.

As well as Clause 8.2.2 in ISO 13485, ***Complaint Handling***, the manufacturer must maintain records of the review, evaluation, investigation, for any complaints involving

¹ <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qsr-regulationmedical-device-current-good-manufacturing-practices-cgmp>

the possible failure of a device, labelling, or packaging to meet any of its specifications.

In adhering to Clause 7.5.4 in ISO 13485, ***Servicing Activities***, the manufacturer must record the information listed in § 820.35(b), at a minimum, for servicing activities.

Under § 820.35(c), in addition to the requirements of Clauses 7.5.1(Control of Production and service provision), 7.5.8(Identification), and 7.5.9(Traceability) of ISO 13485, the ***UDI*** must be recorded for each medical device or batch of medical devices.

Device labelling and packaging controls (§ 820.45). In addition to the requirements of Clause 7.5.1 of ISO 13485, Control of production and service provision, manufacturers must document and maintain procedures that provide a detailed description of the activities to ensure the integrity, inspection, storage, and operations for labelling and packaging during the customary conditions of processing, storage, handling, distribution, and as appropriate, use of the device, including requirements to ensure labelling and packaging have been examined for accuracy prior to release or storage (§ 820.45(a)), the release of the labelling for use must be documented in accordance with Clause 4.2.5 of ISO 13485 (§ 820.45(b)), and results of the labelling inspection in § 820.45(c) must be documented in accordance with Clause 4.2.5 of ISO 13485.

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