FDA'S FINAL RULE OVERVIEW OF QUALITY SYSTEM (QS) REGULATION/ MEDICAL DEVICE CURRENT GOOD MANUFACTURING PRACTICES (CGMP)

Background

In 1987, the International Organization for Standardization (ISO) issued the first version of ISO 9001, a standard intended to define the basic requirements, structure, responsibilities, and procedures required to implement an effective quality management system for manufacturing organizations in general.

In 1996, the International Organization for Standardization issued the first version of ISO 13485, "Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001," to specify, in conjunction with the application of ISO 9001, the Quality Management System (QMS) requirements for medical device manufacturers.

Today, ISO 13485 is used internationally by many regulatory authorities as the foundation for defining regulatory QMS requirements for medical device manufacturers and is utilized in regulatory harmonization programs such as the Medical Device Single Audit Program (MDSAP).

Over time, ISO 13485 has evolved, with the current editions (ISO 13485:2016) becoming more closely aligned with the current requirements set forth in Food and Drug Administration (FDA) 21CFR part 820 QS regulations.

FDA Quality System Regulations: Scope of Changes

The FDA recognizes the similarities between the current Quality System (QS) regulations (21CFR820) and ISO 13485:2016 and is therefore taking the opportunity to harmonize 21CFR part 820 QS by amending sections of the QS for closer alignment with ISO 13485:2016. The revised QS will be renamed the Quality Management Systems Regulations (QMSR). With a couple exceptions, the majority of changes to the QS are intended to align terminology between QS and ISO 13485 regulations. However, there are some more significant changes as follows:

- **21CFR830.35, Control of Records**
  - Revised for alignment with ISO 13485:2016 clause 4.2.5, to specifically address UDI.
  - Requirements for control of records, especially around certain records that interface with other requirements in the FD&C Act such as records of complaints and servicing activities required by part 803, Medical Device Reporting and UDI in accordance with part 830, Unique Device Identification (specified in § 820.35 of the final rule).
- **21CFR820.40, Control of Device Labeling and Packaging**
  - ISO 13485 does not specifically address the inspection of labeling by the manufacturer. Therefore, the FDA is retaining the existing QS, which provide stronger controls for labeling and packaging operations requirements, and carrying them forward to the QMSR.
- **21CFR180(c), Records – General Requirements**
  - Under the current QS requirements, manufacturers are not obligated to share certain quality records such as management review records, internal quality audit reports and supplier audit reports, to FDA inspectors. This is an exception unavailable to manufacturers inspected by other regulators or audited by other entities (e.g., MDSAP auditing organizations). For global harmonization, the FDA has removed this exception in the QMSR final rule.

The current FDA QS regulations use terms such as Device Master Record (DMR), Design History File (DHF), and Device History Record (DHR), which do not appear in ISO 13485 and are not separately defined in the QMSR final rule. Going forward, US Medical device manufacturers should refer to these tile types as the Medical Device File (MDF), as they are currently referred to in ISO 13485.

Discussion

On February 2, 2024, the FDA issued a final rule amending the medical device current Good Manufacturing Practice (cGMP) requirements QS regulations with the intention harmonizing and modernizing the QS regulation for closer alignment with ISO 13485:2016.

Today, the participating MDSAP countries are Australia, Brazil, US FDA, Canada, and Japan. Under the MDSAP program, audits performed by an Auditing Organization (AO) are conducted to ensure compliance with the ISO 13485 requirements and any additional country-specific requirements.

The output audit report is then shared with participating country regulatory authorities. This reduces the need for independent audits of medical device manufacturers to be conducted by each participating regulatory authority. Of course, each participating country has the option to also conduct their own audit of a manufacturer depending on the audit results.

The FDA conducted a thorough review and comparison of ISO 13485 and the QS regulation and concluded that very few FDA-specific requirements needed to be added to the MDSAP audit model, demonstrating not only the similarities between the QS regulation and ISO 13485, but also the comprehensive QMS approach provided by ISO 13485. This has allowed FDA to accept certain MDSAP audits as a substitute for its own routine surveillance of device quality systems, reducing audit redundancies and lightening the audit burden on the FDA and medical device manufacturers.

Benefits for FDA's QMSR Harmonization with ISO 13485

The harmonization of the FDA QMSR with ISO 13485, it is expected to reduce the audit and financial burdens on medical device manufacturers by streamlining regulatory requirements, eliminating redundancies such as audits, and cost reductions associated with maintaining two quality systems. Additionally, it is anticipated that this effort will increase consistency in device manufacturing and production as well as have a more robust quality management system in place.

Since most medical device manufacturers are already compliant with ISO 13485 and MDSAP, implementation of the new FDA QMSR is not anticipated to be burdensome to the medical device manufacturing community.

Moreover, with the FDA aligning its QMSR for essentially the first time since 1996, the regulation requirements can now be streamlined to match today's manufacturing environment. Implementation of a complaint QMS directly correlates to a higher quality product, process efficiencies, with an end result of lower risk to patients.

Additionally, the FDA will review and update the current QSIT and develop a new inspection process to align with the requirements of the new QMSR, to be implemented when the rule takes effect (February 02, 2026).

As revisions are made to the ISO 13485 standard, the FDA will review and evaluate what impact the changes may have and adjust the QMSR when deemed appropriate and necessary.

Important Date(s)

The final ruling was published on February 02, 2024, with a two-year transition period for medical device manufacturers to fully comply with the QMSR. There will be no enforcement of the QMSR until expiration of the two-year transition period, effective February 02, 2026.

For more details, please refer to the FDA's final ruling and FAQs:

- Quality System (QS) Regulation/Medical Device Current Good Manufacturing Practices (CGMP) | FDA
- Quality Management System Regulation: Final Rule Amending the Quality System Regulation – Frequently Asked Questions