Quality Management System Regulation Transition

The FDA's Quality Management System Regulation (QMSR) modernizes the existing QSR, aligning it with the global ISO 13485:2016 standard.

This regulatory overhaul is designed to streamline quality management, elevate risk management, and foster global operational excellence. Medical device companies must now undertake a comprehensive review and potential transformation of their quality management practices and QMS. This requires updating procedures, explicitly integrating risk management, and ensuring their systems are robust, compliant, and prepared for the impending deadline.

For companies that already have QMS compliant to the QSR, the FDA expects that the transition from the QSR to QMSR is completed by 2 February 2026.

As your trusted partner, wega is pleased to offer comprehensive QMSR services tailored to support medical device companies navigating these key changes to FDA's regulatory requirements before the February 2026 deadline.

Our Services Include:

Gap Analysis:
of your current QMS against QMSR, with the goal of identifying gaps and areas for improvement.

Transition Planning:
Develop a transition plan that ensures resolution of gaps identified in the gap analysis.

Updates to Documentation:
Support review and update your QMS documentation to meet ISO 13485:2016 and QMSR requirements.

Employee Training:
Educate and train your team on the changes

Internal Audit:
Plan and conduct an internal audit to ISO 13485:2016 to verify implementation of QMSR.

wega Informatik AG
St. Alban-Graben 3
4051 Basel

info@wega-it.com
+41 (61) 270 87 87

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