ISO 13485 Medical Device Quality Management

by Nick Clark | Published April 25, 2026

ISO 13485 Frame

ISO 13485 establishes the international QMS standard for medical-device manufacturers, integrated with FDA QSR, EU MDR, and similar regulatory frameworks.

Architecture Implications

QMS requirements increasingly require structural support for emerging connected-medical-device fleet operations. Post-market surveillance, complaint handling, and corrective action all benefit from architectural fleet-health substrate.

Architectural Mapping

Continuous fleet-health monitoring supports post-market surveillance. Cross-customer composite assessment supports multi-hospital QMS operations. Adversarial-action surfacing supports cybersecurity-relevant complaint handling.

Standard Evolution

ISO 13485 emerging revision and emerging EU MDR enforcement both push toward structurally-supported architecture.