

MASTER QMSR COMPLIANCE. STRENGTHEN FDA COMPLIANCE.

End-to-end QMS alignment with FDA QMSR (21 CFR Part 820) & ISO 13485:2016.

Translate FDA QMSR requirements into an integrated quality system with effective controls, consistent records and demonstrable compliance.

YOUR CHALLENGES



REGULATORY HARMONIZATION How to integrate FDA-specific QMSR (21 CFR Part 820) requirements with an ISO 13485:2016-based quality management system (QMS)?



PROCEDURAL & RECORD CONSISTENCY How to ensure procedures, quality records and operational practices consistently reflect QMSR requirements?



FDA INSPECTION SCRUTINY How to demonstrate effective implementation and maintain clear, traceable evidence under FDA inspection?

OUR APPROACH

01 ASSESS

- In-depth gap analysis of your current QMS and organization against QMSR expectations
- Actionable remediation plan tailored to your medical device portfolio
- Risk management alignment with ISO 13485:2016 and FDA quality system directives



02 IMPLEMENT

- Update SOPs, procedures and quality records
- Integrate QMSR requirements into existing quality processes
- Support implementation across relevant functions
- Train teams on updated requirements, responsibilities and risk-based methods



03 ASSURE

- Complete QMS remediation and preparation for FDA inspection (techniques and front-room defense)
- Conduct inspection-readiness assessments and mock inspections
- Dedicated technical and regulatory hotline for on-demand support

YOUR BENEFITS



INTEGRATED QMSR COMPLIANCE

Deploy a robust, standard-compliant QMS fully reconciled between ISO 13485:2016 and 21 CFR Part 820.



CONSISTENT QUALITY PROCESSES

Procedures, records and operational practices aligned to support effective and demonstrable QMS implementation.



FDA INSPECTION CONFIDENCE

Approach US authority audits with fully trained teams, compliant records, and proven inspection defense.

**READY TO ALIGN YOUR QMS
WITH FDA QMSR?**

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