SERVICE SHEET

QMSR Gap Assessment

FDA QMSR & ISO 13485:2016 readiness for medical device manufacturers · Dallas, Texas

Know your gaps before the investigator does.

A structured, risk-based review of your quality system against the QMSR, ISO 13485:2016 and FDA's new inspection approach – with a clear roadmap to close the gaps.

> *"What hasn't been recorded, hasn't happened."*

THE CHALLENGE

Since February 2, 2026, FDA's Quality Management System Regulation (QMSR) incorporates ISO 13485:2016 into 21 CFR Part 820, and inspections follow the risk-based Compliance Program 7382.850 instead of QSIT. Management review, internal audit and supplier audit records are now open to investigators. Many quality systems were updated on paper – the question is whether they hold up in an inspection.

WHAT WE ASSESS

- **QMS foundation** – procedures, terminology and training updated to the QMSR and ISO 13485:2016, plus the FDA-specific requirements that still apply (e.g. records, labeling and packaging controls, MDR, corrections and removals, UDI)
- **Management oversight** – management review, quality objectives, internal audits and how risk drives decisions
- **Design and development** – design controls, risk management file, design changes
- **Production and service provision** – process and software validation, traceability, labeling, equipment
- **Outsourcing and purchasing** – supplier selection, quality agreements, supplier audits
- **Change control** and **measurement, analysis and improvement** – complaints, MDR decisions, nonconformities, CAPA effectiveness, trending

HOW IT WORKS

1. **Free 30-minute introductory call** – your situation, products and timelines.
2. **Scoping** – sites, product families and processes in scope; fixed agenda and document request list.
3. **Document and record review** – procedures and real records, sampled by risk.
4. **Interviews and process walk-throughs** – on site, remote or hybrid, along the six QMS areas of CP 7382.850.
5. **Gap report and management readout** – risk-rated findings and a prioritized remediation roadmap.

WHAT YOU RECEIVE

- Gap report with findings rated by patient and compliance risk, each linked to the requirement
- Prioritized remediation roadmap with suggested owners and realistic sequencing
- Management readout – clear status for leadership, ready for your next management review
- Optional support to close the gaps: procedures, CAPA, supplier controls, training and test inspections

WHO IT'S FOR

Medical device manufacturers and contract manufacturers supplying the US market – from start-ups preparing for their first inspection to established sites with legacy QSR systems.

FORMAT

On site in your facility, remote or hybrid

SCOPE

One site, a product family or the complete QMS – agreed upfront

DURATION

Depends on scope and size; fixed in the proposal after scoping

YOUR TEAM

Thomas Buettner and Johanna C. Buettner, supported by our European partner qteam service GmbH where needed

GOOD TO COMBINE WITH

Remediation planning · CAPA effectiveness · supplier audits · behavior training and test inspections

CONFIDENTIALITY

Your data and findings are treated confidentially; NDA on request

START A CONVERSATION

Free 30-minute introductory consultation

Find out where your quality system stands – without obligation.

Scan to book →

qteam service LLC · 13355 Noel Rd, Ste 1100, Dallas, TX 75240 · info@qteam-service-llc.com · www.qteam-service-llc.com

Engagement scope, timing and deliverables are subject to agreement. · Rev. November 2026