CAPABILITY STATEMENT

qteam service LLC

Quality, regulatory & compliance consulting for healthcare and life sciences · Dallas, Texas

Our support for your quality.

Even the most advanced companies and innovative products sometimes need some support. Our mission is to align your brilliant ideas with the global requirements.

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

COMPANY OVERVIEW

Founded in Dallas, Texas in April 2025, qteam service LLC provides specialized, hands-on support to healthcare and life sciences organizations: quality management, regulatory compliance, process improvement and targeted operational support. We work alongside internal teams with a practical, risk-based approach – from building a quality system to supporting audits, inspections, transfers and acquisitions.

CORE COMPETENCIES

- **Management systems** – quality, regulatory, risk and supplier – design, implementation and maintenance
- **Process & performance optimization** – leaner processes, lower cost of quality, no compromise on compliance
- **FDA QMSR & ISO 13485:2016** – gap assessments, remediation planning, inspection readiness
- **Complaints, nonconformities & CAPA** – investigation, root cause, effectiveness checks
- **Supplier quality** – risk-based controls for suppliers and outsourced processes, supplier audits
- **Qualification & validation** – equipment, processes and systems
- **Manufacturing transfers** – between sites and manufacturing partners
- **M&A, integration & relocations** – due diligence, QMS harmonization, site moves
- **Audits & inspection readiness** – internal audits and preparation for authorities, notified bodies and customers
- **Training & audit simulations** – inspection behavior training, test audits, unannounced test audits
- **Clinical information systems & reimbursement** – targeted support for providers and manufacturers
- **Rapid-response support** – recalls, product issues, urgent audits – scope agreed per engagement
- **Notary Public** – commissioned in Texas, by appointment

WHY QTEAM SERVICE LLC

- **Hands-on delivery** – practical results that complement your internal teams and hold up in audits and inspections
- **Inspection-focused** – aligned with FDA's QMSR and the risk-based inspection approach of Compliance Program 7382.850
- **Transatlantic perspective** – US-based consulting together with our European partner, qteam service GmbH
- **Discretion & professionalism** – client details are treated confidentially; references and project disclosures require client authorization

HOW WE ENGAGE

Project-based consulting · Targeted readiness assessments · Interim capacity and rapid-response support · Trainings and audit simulations · Implementation support

INDUSTRIES SERVED

Life sciences & biotechnology · Medical devices · Pharmaceuticals · Hospitals & healthcare providers · Emergency medical services · Fire departments

COMPANY

qteam service LLC
Texas limited liability company
Founded April 2025

ADDRESS

13355 Noel Rd, Ste 1100
Dallas, TX 75240, USA

LEADERSHIP

Thomas Buettner – Chief Executive Officer, Notary Public (TX)
Johanna C. Buettner – Chief Operating Officer, Notary Public (TX)

NAICS CODES

541611	Administrative & General Management Consulting
541618	Other Management Consulting Services
541690	Other Scientific & Technical Consulting
611430	Professional & Management Development Training

CONTACT

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LinkedIn: qteam-service-llc

START A CONVERSATION

Free 30-minute introductory consultation

FDA QMSR 2026 readiness, audits, trainings or rapid support – book a time online.

Scan to book →