SERVICE SHEET

Training & Test Audits

Audit and inspection readiness for healthcare and life sciences · Dallas, Texas

Be ready – before the auditor arrives.

Behavior training, test audits and unannounced test audits that prepare your people and your organization for authorities, notified bodies and customers.

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

WHY IT MATTERS

Audits and inspections are decided not only by procedures and records, but by how your people present them. Under FDA's risk-based inspection approach and with notified body and customer audits becoming more demanding, preparation must cover both: a quality system that works – and a team that can show it with confidence.

OUR OFFERINGS

01

Behavior training for audits & inspections

How to act when the auditor or inspector is in the room: answering accurately and to the point, presenting records with confidence, handling document requests and escalations, front room and back room working smoothly together.

Format: interactive workshop with role plays for management, subject matter experts and operational staff.

02

Test audits before mock audits & inspections

A structured test audit ahead of your planned mock audit or inspection. We review processes and records against the applicable requirements, identify gaps early and help you close them – so the mock audit confirms readiness instead of revealing surprises.

03

Unannounced test audits

Would you pass if the inspector arrived today? Agreed with your management in advance, we perform test audits without notice to the organization – showing how ready you really are in daily operations.

WHAT YOU RECEIVE

- Training tailored to your products, quality system and the audits you expect – FDA, notified bodies, customers
- Training materials and attendance records for your training files
- Audit report with findings, observations and practical recommendations
- Debrief with management and the audited teams – what went well, what to fix before the real audit

WHO IT'S FOR

Medical device, pharmaceutical and life sciences companies, hospitals and healthcare providers preparing for audits and inspections

TYPICAL TOPICS

- Inspection logistics: front room, back room, document requests
- Answering questions – facts, scope, no speculation
- Presenting CAPAs, complaints and risk files
- Subject matter expert preparation and storyboards
- Escalation and daily debriefs

FORMAT

On site or remote; length and group size agreed per engagement

FRAMEWORKS

FDA QMSR and CP 7382.850 · ISO 13485:2016 · notified body and customer audits

TRAINERS

Thomas Buettner and Johanna C. Buettner

START A CONVERSATION

Free 30-minute introductory consultation

Plan a training, test audit or unannounced test audit for your team.

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