TOTAL QUALITY EXCELLENCE

Precision. Integrity. Confidence.

CAPABILITIES STATEMENT

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WHO WE ARE

Total Quality Excellence (TQE) is a fractional and full-time affiliated consulting group specializing in quality system development, regulatory compliance, and operational excellence across the life sciences and medical device sectors.

We bring more than four decades of combined quality leadership across medical devices, biotechnology, pharmaceuticals, radiopharmaceuticals, and cell and gene therapy — from a start-up's first quality system to global organizations operating across multiple sites and health authority jurisdictions. We work across both sides of a combination product — device and pharma — from design through inspection readiness, led by practitioners who've done the job themselves, not just advised on it.

WHAT WE DO

Quality & Compliance Strategy	QMS design, implementation and optimization · FDA QMSR transition and remediation · quality governance and Management Review · phase-appropriate systems for scaling organizations
Audit & Risk	Independent Lead Auditor · internal and supplier audits · third-party and MDSAP audit preparation and hosting · risk management under ISO 14971 and ICH Q9 · CAPA effectiveness review
Inspection Readiness	FDA, EMA, MHRA, TGA and Health Canada preparation · mock inspections and gap assessments · investigator interview coaching · post-inspection response and remediation
CMC & Validation	Process validation and PPQ execution · method validation and transfer · specification development · stability program design and reporting · OOS and OOT investigations · mix and compatibility studies · PAI readiness
Supplier, CDMO & Partner Oversight	Client-side CDMO leadership · API and contract partner management · quality governance · supplier qualification and performance management · quality agreements · supplier change control and audit programs
Quality Systems & Data Integrity	Deviation, CAPA and change control · document and records control · complaint handling and post-market surveillance · data integrity and ALCOA++ · 21 CFR Part 11 and Annex 11
eQMS Implementation	Platform selection and vendor qualification · configuration and validation (IQ/OQ/PQ) · paper-to-electronic migration · business system ownership · metrics and dashboards
Device-Specific Services	Design controls and design history files · ISO 13485 · EU MDR and IVDR transition · PRRC support under MDR
Training & Leadership	Inspection readiness training · GxP training programs and LMS administration · quality culture and governance development · auditor mentorship

HOW WE ENGAGE

- **Fractional leadership —** acting as Head of Quality, Management Representative, or Quality Systems lead on retainer
- **Full-time placement —** for organizations that need the role permanently filled
- **Project engagement —** an inspection, a gap assessment, a QMS build, a remediation program, a single audit
- **Audit services —** independent lead auditing on a scheduled or as-needed basis

Engagements are scoped quickly and start fast, with an honest read on fit from day one — and a referral if we're not it.

INDUSTRIES SERVED

Sectors	Medical devices · Biotechnology · Pharmaceuticals · Radiopharmaceuticals · Cell and gene therapy · In-vitro diagnostics · CDMO and CMO organizations
Stage & reach	Venture-backed start-ups through multi-site global organizations · United States and international, supporting FDA, EMA, MHRA, TGA, Health Canada and SwissMedic interactions

REGULATORY FRAMEWORKS AND STANDARDS

United States	21 CFR Part 820 (QMSR) · 21 CFR Part 210 and 211 · Part 4 (combination products) · Part 11 · Part 803 (MDR) · Part 806 (corrections and removals)
International	ISO 13485:2016 · ISO 14971:2019 · ISO 10993-1:2025 · IEC 62304 · IEC 60601-1 · ICH Q7, Q9(R1) and Q10
Europe & UK	EU MDR 2017/745 · EU IVDR 2017/746 · EUDAMED · EU GMP Annex 11 · UK Medical Devices Regulations 2002 and UKCA · UK post-market surveillance requirements
Audit programs	MDSAP (FDA, Health Canada, TGA, ANVISA, MHLW/PMDA) · GxP compliance audits across GMP, GLP and GCP · TÜV audit experience

SYSTEMS AND PLATFORMS

eQMS & documents	Veeva Vault (QMS and DMS) · TrackWise · MasterControl · AssurX
Learning & analytics	ComplianceWire · Plato · Plateau · Spotfire · Power BI · Smartsheet
Other	Audit Utopia · SAP-QM · ERP and LIMS integration · AI-enabled compliance and audit simulation tools

SELECTED RESULTS

Inspection outcomes	Zero FDA observations on a first-time inspection management program · successful FDA Pre-Approval Inspection readiness
Certification	MDSAP ISO 13485:2016 certification and CE Mark approval delivered for a Class III device · ISO 13485 accreditation across device organizations
System performance	Deviation on-time closure raised from 82% to 100% · deviation recurrence reduced by 64% · change control backlog reduced by 61% · process redundancies reduced by 43% · audit findings reduced by up to 40%
Commercialization	Quality management system built from the ground up, carried through to commercial launch · validation and process performance qualification execution for FDA submission readiness
Scale	Global frameworks across sites · post-market surveillance for a $500M+ portfolio · APQR programs covering $100M+ portfolios · supplier programs spanning 100+ approved vendors

START A CONVERSATION

If your organization is preparing for an inspection, developing a new quality system, working through the FDA QMSR transition, or pursuing operational excellence, TQE can provide the expertise and leadership to get you there.

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