Capability Statement

Company Overview

Quality Systems Services, LLC is a small consulting firm that works with pharmaceutical and medical device companies to navigate the complexities of compliance.

We are committed to assisting FDA-regulated companies in creating and maintaining a well-functioning quality system to ensure compliance with standards and regulations, improve product or service quality, reduce costs, enhance customer satisfaction, and promote continuous improvement and innovation.

Core Competencies

- Quality System Implementation
- Quality System Remediation
- Audit Support
- FDA Commitment Resolution

Differentiators

- Provides solutions tailored to specific business needs.
- Successfully completed multiple FDA commitments
- Certified as a Certified Quality Auditor through ASQ

Past Performance (as a subcontractor to larger consulting firms)

- Fortune 500 biologics company assigned as leader of a 7-person team to address an FDA untitled letter regarding complaint investigations. Created sample selection of complaint investigations to be reviewed, reviewed 200+ complaints, and drafted detailed report of findings and recommendations.
- Global medical device company assigned to address a CAPA for an FDA commitment regarding risk classification and reportability assessments in complaint files. Reviewed 300+ complaints, summarized findings and wrote summary report to be used in CAPA closure.
- Virtual startup biologics company in Phase 3 clinicals assigned to review current SOPs and facility documents and provide expert opinion to aid company in preparation for commercialization.
- Radiopharmaceutical (50+ employees) subsidiary of a Fortune 500 pharmaceutical company assigned to address site QMS issues including deviations, CAPAs, EM, training and complaints. Site passed the next FDA inspection.
- Fortune 500 biologics company assigned as Interim QA review third party team to review batch records prior to release of products for FDA commitment.

Previous Experience

- Small virtual dental products (medical device and pharmaceutical) subsidiary of larger dental supply company as QA/RA Manager and ranking Site Head of QA. Managed team of three, performed supplier audits, managed two recalls, and was management representative for all regulatory inspections and notified body audits. Remediated QMS based on assessment from parent company.
- Global pharmaceutical and biologics company went from Compliance Specialist to QA Lab Validation Manger. Remediated QMS for development QC group, QA Leader for new laboratory building for over 100 employees from Chemistry, Biochemistry and Microbiology.
- Global company was an employee of the Diagnostics (medical Device) division. Manufacturing, QC and investigated deviations. Moved to Consent decree remediation to work on commitment in rapid testing production. Moved to R&D and did discovery then design control for new tests.

Quality Systems Services, LLC

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