



JQCS CONSULTING

NAICS Codes:
541330, 541611, 541690, 541614
DUNS#: 04-294-3179
CAGE#: 9V6J1
www.jqcsconsulting.com
csoriano@jqcsconsulting.com
321-284-6345

CAPABILITY STATEMENT

ABOUT US

JQCS Consulting, a nationally certified Small Business with the NMSDC (National Minority Supplier Diversity Council), offers a full range of services for high-volume and highly regulated industries, including biopharma, pharmaceutical, medical device, and combination product manufacturers, as well as government agencies. Our team can assess existing processes, identify areas for improvement, and implement new solutions to meet specific requirements. From initial concept to project delivery and ongoing support, JQCS is committed to providing efficient solutions in a timely manner, minimizing the impact on production schedules.

Our team comprises professionals with extensive experience in the biopharma, pharmaceutical, medical device, and combination product industries. While educational disciplines may vary, our team mainly consists of individuals with backgrounds in engineering, chemistry, microbiology, and computer science, among others. At JQCS, cGMP is embedded in our culture, alongside integrity and professionalism. Therefore, all work performed by JQCS Consulting, regardless of project size or industry, is delivered with the highest quality in mind. We believe that exceeding client expectations is the only way to successfully complete a project.

OUR VISION

To become the number one solution provider in the Life Science Sector, JQCS Consulting aims to deliver consistent solutions that exceed all expectations while providing the highest quality of work. JQCS Consulting also aims to be a solution provider to the government, leveraging its extensive experience in the life science sector to support government agencies in all their needs.

OUR MISSION

UNDERSTAND

From the project's inception, ensure a thorough understanding of its goals, tasks, deliverables, and any challenges that may arise in order to successfully complete it.



COMPLETE

Execute all project tasks and deliverables within the agreed timeline and budget, ensuring that all aspects of the project are successfully implemented and completed while maintaining the highest standards of quality and compliance. Our team is dedicated to upholding regulatory requirements, including cGMP and other relevant standards, to ensure the safety, efficacy, and integrity of the products and services we deliver.



IMPROVE

Continuously evaluate operational processes and outcomes to identify areas for enhancement, implementing innovative solutions to improve operational efficiency and effectiveness.



EXCEL

Consistently surpass client expectations by delivering exceptional results within the expected budget and timeline.



DIFFERENTIATORS

- **Diverse Industry Coverage:** JQCS Consulting offers services across a broad spectrum of industries, including biopharma, pharmaceuticals, medical devices, and combination products, ensuring expertise across multiple sectors. We also serve the government, demonstrating our ability to navigate complex regulatory environments and deliver high-quality solutions across diverse sectors.
- **Comprehensive Approach:** The team assesses existing processes, identifies areas for improvement, and implements tailored solutions to meet specific industry requirements, providing end-to-end support from concept to project delivery.
- **Experienced Team:** The consultants at JQCS Consulting bring extensive industry experience and a wealth of knowledge from backgrounds in engineering, chemistry, microbiology, computer science, and other relevant disciplines.
- **Quality and Compliance Focus:** The company's culture is deeply rooted in cGMP principles, integrity, and professionalism, ensuring that all projects—regardless of size or industry—are delivered with the highest quality standards in mind.
- **Client-Centric Approach:** JQCS Consulting is committed to exceeding client expectations, viewing this as the only path to successful project completion. The team emphasizes efficiency and timeliness to minimize disruptions to production schedules.

SERVICES

JQCS Consulting offers a diverse range of services to address the complexities of the life sciences sector.

Core services include:

- Audits and Mock Inspections
- Artificial Intelligence
- Automation and System Validation
- Commissioning, Qualification, and Validation
- Engineering
- Information Technology
- Laboratory Services
- Lean Manufacturing
- Process Engineering
- Process Improvement
- Project Management
- Quality Risk Management
- Quality Systems
- Regulatory Affairs
- Regulatory Compliance
- Steam in Place Validation and Engineering
- Technology Transfer
- Training

PAST PERFORMANCES



JQCS Consulting spearheaded the assessment and enhancement of absorbable and non-absorbable suture manufacturing processes, optimizing yields, minimizing waste, and increasing output. Additionally, they developed and implemented Preventive Maintenance inspection systems integrating ultrasound technology. As pivotal members of the High Speed braiding project team, they conducted extensive research to develop essential User Requirement Specification for next-generation braiders. They also conducted in-depth current and future capacity studies for suture making. JQCS Consulting managed all validation activities, from Factory Acceptance Test (FAT) in Germany to the execution and implementation of IQ/OQ/PQ protocols and implementation. Presently, they oversee global validation efforts for three projects spanning five Ethicon sites worldwide, including USA, Mexico, Brazil, Puerto Rico and Germany.



JQCS Consulting provided essential resources as part of a collaborative effort to support Catalent Sites for US FDA Pre-Approval Inspections, ensuring Quality Management System readiness for an upcoming commercial launch. This involved assessing deviations, implementing corrective actions, and ensuring timely closure. JQCS Consulting also investigated deviations, partnered with CAPA engineers for root cause analysis, and provided project management services, including weekly status meetings, guidance, and deliverable metrics. They collaborated with Catalent's Quality, Manufacturing, Science, and Technology teams to ensure proper impact assessments, document gaps, provide recommendations for traceability, and identify Subject Matter Expert needs for Pre-Approval Inspections based on critical knowledge.

FOUNDERS EXPERIENCE

