

The STEM Consulting Group LLC

CAGE: 08Q61

DUNS: 012345

CAPABILITY STATEMENT

SBA WOSB-certified and GDOT-recognized firm

Expertise in regulatory intelligence, documentation, validation, risk assessment, and stakeholder training

AI-enabled compliance and data strategy solutions for future regulatory readiness

COMPANY OVERVIEW

The STEM Consulting Group LLC is a boutique advisory firm specializing in regulatory compliance, risk management, and quality systems across biotech, medical devices, engineering, and research institutions. Unlike large generalist consultancies, we focus exclusively on STEM industries, delivering practical, measurable outcomes that reduce risk, improve efficiency, and ensure long-term compliance success.

DIFFERENTIATORS



Proactive Problem Solving

Identifying and mitigating risks before they escalate



Data-Driven- Impact-Measurable improvements in efficiency and profitability



Industry Leadership -

Thought leadership, published research, and regulatory advocacy



Ethical Innovation -

Integrity-driven compliance solutions

Industry Recognition & Experience

Biotech

ISO & ASQ certification alignment

Medical Technology Developers

Regulatory affairs strategy and submissions

Engineering Enterprises

Engineering enterprises Risk mitigation for emerging technologies

Research Institutions

Advisory, speaking engagements, and published thought leadership

CORE COMPETENCIES

Regulatory Compliance Assessment & Risk Management
Quality System Optimization & Implementation
Strategic Regulatory Advising
Audit Readiness & Long-Term Compliance Success

Data Strategy & AI-Enabled Compliance – Leveraging advanced analytics and machine learning to strengthen risk management, audit readiness, and regulatory intelligence

Documentation & Submission Expertise (FDA 510(k), IND, PMA, eCTD)
Risk Assessment & Decision Support (FMEA, ISO 14971, HACCP)
Stakeholder Communication & Training

Regulatory Intelligence & Monitoring
Validation & Verification (process, equipment, software)

Proven Results

95% - Compliance - Regulatory alignment for biotech and engineering clients
80% Faster Turnaround- Streamlined compliance processes
80 % Reduction in audit findings- Optimized quality systems that improved inspection outcome
\$\$\$ Cost Savings- Reduced risk exposure and avoided penalties

Contact us

Website: thestemconsultinggroup.com

Email:

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Future Outlook

STEM Consulting Group is preparing clients for the next wave of regulatory challenges:

- **AI/ML in Medical Devices** – Supporting compliance with FDA guidance and EU AI Act requirements
- **Digital Transformation in Compliance** – Helping organizations adopt advanced data governance and predictive analytics tools
- **Global Regulatory Convergence** – Advising on harmonization of standards across U.S., EU, and international markets
- **Sustainability & ESG Compliance** – Aligning regulatory strategies with environmental and social governance expectations