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## ABOUT US

### **QuRA Solutions, where precision meets compliance**

We specialize in comprehensive quality and regulatory affairs consulting services, tailored to meet the unique needs of your organization. Our commitment to excellence will elevate your quality standards and ensure that regulatory compliance is seamlessly integrated into your operations.

## Our core offerings

- ✓ **Quality Management Systems (QMS)**
  - Design, implement, and manage robust QMS including all Standard Operating Procedures and records under ISO 9001/ 13485; ISO 17025, 21CFR820 (FDA-GMP); CAP/ CLIA/ GLP/ GCLP.
  - Tailored solutions for industry-specific needs.
- ✓ **Regulatory compliance**
  - FDA submissions including 510(k), De Novo, and Breakthrough device applications.
  - Clinical trial design, and support, including all IRB interactions, and Clinical Protocol Management.
  - Ensure your business meets all requirements (45CFR46, 21CFR210, 21CFR211, 21CFR11).
- ✓ **Design and development expertise**
  - Leverage our proficiency in design and development for comprehensive solutions specifically for medical devices per ISO 13485.
  - Seamlessly integrate design controls, quality, and regulatory elements into your product/ process development and research projects.
- ✓ **Risk assessment**
  - Identify and assess potential risks per ISO 14971.
  - Implement proactive strategies to mitigate risks and ensure compliance.
- ✓ **Audit and assurance**
  - Thorough audits to identify areas for improvement and ensure compliance with industry standards.
- ✓ **Training and Education**
  - Empower your team with knowledge and skills.
  - Sustain quality and regulatory excellence.

## Why QuRA Solutions?

- ✓ **Proven track record**
    - Seasoned professionals with diverse industry experience.
    - History of successful audits.
    - Consistent performance with no findings or observations during inspections, reflecting our meticulous approach and expertise.
  - ✓ **Client-centric approach**
    - Your success is our priority.
    - Tailored solutions to meet your specific needs, ensuring a partnership built on trust and transparency.
  - ✓ **Innovation-driven solutions**
    - Future-proof your operations.
    - Embrace forward-thinking mindsets to fulfill current compliance requirements.
  - ✓ **Validation and Verification Capabilities**
    - Assay and Process.
    - Software including Excel.
  - ✓ **Technical writing expertise**
    - Ensure clear, precise, and compliant documentation.
    - Enhance communication and understanding of your processes and procedures.
  - ✓ **Project management**
    - Strategic thinking, planning, and execution.
    - Precise project definition and goal setting.
    - Meet or exceed timelines, and adaptive adjustments.
    - Proactive management and resource optimization.
- Marketing**
- ✓
    - New Market and Trend Analysis.
    - New product development- concept to launch.