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Director – Medical/In Vitro Device Software Quality Consulting

Founded in 1968, Oriel STAT A MATRIX, a Validant company, is a leading global organization providing consulting and training services to the Regulatory Affairs and Quality Assurance functions within the Life Science industry. We are proud of our focus on client outcomes: we achieve superior client results because we select from a pool of diverse, highly skilled, specialized, commercially minded Quality System and Regulatory Affairs team members. Together, our team executes best-in-class advisory, audit, consulting and training services in the medical/in vitro device market. We are looking for individuals who possess a level of skills, attributes and talents commensurate with our brand.

Our Director – Medical/In Vitro Device Software Quality Consulting roles are home based and require the ability to travel to client sites for delivery or the ability to deliver through virtual technology. We therefore seek highly organized individuals who are self-starters, good communicators and are open to flexible work arrangements, seeking variety in the work they do.

Position Description

The Director – Medical/In Vitro Device Software Quality Consulting is responsible for planning and delivering Life Science software consulting engagements related to quality/regulatory affairs infrastructure. Post holders will also be expected to contribute to the development of software verification and validation intellectual property. Consulting engagements will cover both software embedded into devices and software in stand-alone solutions to be used alongside devices.

Person Description

- Already recognized as an expert by peers and industry professionals
- Confident personality and competent in getting ideas across to others effectively
- Demonstrates ability to work in a team environment, especially when operating remotely
- Passion for patient safety through effective quality assurance and regulatory affairs activities
- Respects the contribution of all colleagues and facilitates consensus on tough issues
- Demonstrates flexibility in day-to-day working in the team and in approach to unique client issues
- Ability to assimilate diverse data, think critically and solve problems
- Strong understanding of existing and emerging global regulation over patient and data privacy
- Strong understanding of the threat and activities to mitigate cybercrime
- Evidence of experience with 15 or more medical/in vitro devices
- Ability and desire to provide formal training courses in some or all these topics *is a major plus*

Basic Qualifications

- Bachelor's degree in Life Sciences, Software Engineering or related field; master's degree preferred
- Evidence of progressively taking more responsibility and leading activities in management or as a high-level individual contributor
- Ability to get ideas across in a workshop format; great at engaging participants in the subject
- Evidence of delivering 15 or more highly technical consulting engagements in software quality assurance

Duties

- Adherence to appropriate quality manuals
- Deliver the work in an engaging and supportive manner, focusing on client need and understanding at all times
- Advise on testing software manually and with automated tools in a testing protocol

- Ensure user interfaces are evaluated for accuracy and ease of use
- Design the management of a testing protocol through software interfaces, public and proprietary
- Evaluate the effectiveness of multiple devices that need to work together to deliver the solution
- Advise on or design unit testing, integration and regression testing and defect removal log techniques
- Embed software version control and link it to the device regulatory documentation
- Establish defect logs for issues found during V&V and make sure all are closed off satisfactorily
- Design of methods to prevent data breaches and cybercrime

Industry Requirements

- Experience with medical/in vitro device manufacturing, interpretation and application of codes, regulations, and standards that relate to the use of software in medical/in vitro devices
- Experience with quality systems planning and implementation, design control and software verification/validation
- Strong knowledge of a range of software development, testing and regression methodologies

Travel

Ability to travel extensively domestically (30% - 50%). Occasional international travel may be required.

To Apply

Email your resume and a cover letter to hr.tech@orielstat.com.
Please place "Job Code: DSQC" in the subject line.

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