1095 Morris Avenue, Suite 103B
Union, NJ 07083
Phone: 800.472.6477
Email: tech.hr@orielstat.com
Website: www.orielstat.com

Director – Medical/In Vitro Device Artificial Intelligence

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 Artificial Intelligence 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. We are also seeking trendsetters who want to push the capabilities of AI.

Position Description

The Director – Medical/In Vitro Device Artificial Intelligence is responsible for planning and delivering Life Science AI-related engagements supporting the emerging use of AI and the quality/regulatory affairs infrastructure. Post holders will also be expected to contribute to the development of artificial intelligence intellectual property, including training modules and consulting and audit tools. Engagements will cover both artificial intelligence embedded into devices and software in stand-alone solutions to be used alongside devices.

Person Description

- Already recognized as an expert by peers and a thought leader in the AI industry
- Confident personality and competent in getting complex ideas across to others effectively
- Demonstrates sound understanding of predictive analytics, continuous monitoring within limits and pattern recognition
- Passion for patient safety through effective quality assurance and regulatory affairs activities
- Demonstrates flexibility in day-to-day working in the team and in approach to unique client issues
- Ability to discern good timing for the issuance of alerts; not too many, never too late
- 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 AI applications, at least some with medical/in vitro devices
- Passion to extend the capabilities and uses of AI in the Life Sciences industry – pushing boundaries
- Ability and desire to consult, audit and train in AI topics *is a major plus*

Basic Qualifications

- Bachelor’s degree in Life Sciences, AI, 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 number of different ways
- Evidence of delivering AI support in consultative or training engagements
- Adept at applying AI techniques not only to medical equipment, but also to consumer equipment that forms part of the solution

Duties

- Advise on design, testing, production and postmarket phases of an AI-related solution
- Create and enhance predictive analytic solutions, pattern recognition and the issuance of medical alerts
- Advise on testing AI solutions 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 and AI solutions that need to work together
- Advise on or design unit testing, integration and regression testing and defect removal log techniques
- Embed version control and link it to the relevant device regulatory documentation
- 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/AI in medical/in vitro devices
- Experience with quality systems planning and implementation, design control and software verification/validation
- Strong knowledge of a range of AI development, testing and regression methodologies
- Strong knowledge of the capabilities and current limitations of the AI industry

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: DAIC" in the subject line.

Find additional jobs at Oriel STAT A MATRIX.
Oriel STAT A MATRIX is an Equal Opportunity Employer.