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Vice President – US Regulatory Affairs

Founded in 1968, Oriel STAT A MATRIX 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 balance a pool of highly skilled, specialized affiliates with a carefully chosen team of expert, commercially minded full-time Quality System and Regulatory Affairs employees, all of whom can execute to best-in-class consulting and training services in the market. Our strategic focus on maintaining a balanced bench of high-caliber affiliates and full-time employees has naturally driven exceptional organic growth for the organization. In addition to this, the growing regulatory environment for medical device quality means we are currently seeking to add key senior delivery roles in our Life Science practices. We are looking for individuals who possess a level of skills and talents commensurate with our brand and a strong ability to deliver engagements, oversee engagements and coach their teams.

We offer a friendly and pleasant office work environment; work schedule flexibility; telecommuting (when business permits); a competitive compensation package including an incentive compensation plan; a generous health benefits package including medical, dental, vision, FSA, life insurance and a 401(k) plan.

Position Description

The Vice President of US Regulatory Affairs will interact with all levels of a client's organization, including but not limited to executive management, regulatory and quality management leaders, line employees, etc. This interaction is imperative for understanding the client's needs, regulatory requirements, and organizational goals, and it ensures that processes and deliverables are documented in a way so as to provide the necessary compliance to identified standards or regulations. This role will also be required to provide oversight of Oriel STAT A MATRIX full time Principal Consultants and independent Affiliate Consultants assigned to Regulatory Affairs and related submission and remediation projects by managing project schedules, conducting regular project update meetings, and reviewing documentation provided by all consultants prior to submission to the client.

The Vice President of US Regulatory Affairs will work in conjunction with peers and the Sr. Vice President of Life Science Consulting and Education to develop, revise, and/or deliver certain training programs for both on-site client engagements and public training seminars. This role will also work with Oriel STAT A MATRIX employees and consultants to develop standard practices and tools necessary to aid in engagements for the Life Science department.

Position Responsibilities

The VP US Regulatory Affairs will accomplish results by:

Engagement Delivery

- Personal delivery of senior level engagements either individually or as part of larger team.
- Ensuring that standardized regulatory consulting projects are designed for consistency (such projects include regulatory strategy development, predicate product assessments and testing requirements, design dossier and technical file evaluations, clinical evidence reviews, regulatory transition projects, etc.).
- Establishing and maintaining clearly defined record keeping to mitigate future risk.
- Ensuring that any customized consulting service is properly scoped during the proposal process, and that appropriate record keeping and monitoring are designed into the service.
- Ensuring that consulting engagement deliverables are provided in accordance with the established timelines agreed upon by the client.
- Overseeing the scoping and execution of all regulatory consulting projects for US-based clients.
- Reviewing results of team members' performance and taking corrective action when necessary.

Engagement Support

- Making sure that consulting processes are documented and scalable (i.e., other consultants can replicate the service).
- Supporting the leadership team in reviewing CVs of potential full time and independent affiliated consultants and actively participating in the vetting and onboarding of candidates selected.
- Training new staff and affiliated consultants on the regulatory consulting services we offer, our philosophy and our methods of delivery.
- Working with the leadership team, determine the necessary mix of consultant and trainer skills required to meet the strategic plan and identify opportunities for team member development.

Leadership

- Translate client needs into relevant deliverables that leverage the firms broad platform of services.
- Develop and implement strategic and tactical account plans.
- Ensure development and coaching of all team members occurs and is effective, with a high degree of personal involvement in their development.
- Provide insight on current trends in the life sciences sector and identify how our life science offerings can be augmented and updated to address these trends.

Basic Qualifications

- Bachelor's degree in Engineering, Regulatory Affairs, Science, or healthcare-related field.
- A minimum of 10 years of experience in a relevant Life Sciences field.
- A minimum of 10 years delivering consulting engagements.
- A minimum of 5 years leading consulting engagements.

Industry Requirements

- Interpretation and application of regulations, and standards in the medical device industry.
- Interpretation of proposed and current changes in legislation and regulation in the medical device industry.
- FDA regulatory compliance, including product submissions.
- MDSAP and/or EU-MDR experience would be a distinct plus.
- Clinical evaluation report writing and assessment.
- Strategy development and deployment.
- Complaint handling; 483 and Warning Letter responses.

Travel

Ability to travel >50% of the time domestically and/or internationally is required for this role, although it is our goal for all staff to be at home over weekends.

To apply, email your resume and a cover letter to hr@orielstat.com. Please place *Job Code: "VP-USRA"* in the subject line.

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Oriel STAT A MATRIX is an Equal Opportunity Employer.