

## VOISIN CONSULTING LIFE SCIENCES CAREERS

Voisin Consulting Life Sciences assists biotechnology, pharmaceutical and medical technology companies in the design and implementation of innovative and global regulatory strategies to expedite product development. Products include drugs, biologics, medical devices, *In-Vitro* Diagnostics, combination products, cell, gene and tissue therapies and borderline products including nutraceuticals and cosmeceuticals. We collaborate with start-ups and medium-sized companies to bring products to the market in the most efficient and cost-effective manner, within evolving regulatory frameworks.

VCLS offers various career opportunities to Regulatory Affairs professionals of all nationalities in the USA, Switzerland, India, and Singapore.

### OPEN POSITION:

### REGULATORY AFFAIRS - IVD and MEDICAL DEVICES

Located: *VC-US- Cambridge, MA Office*

#### **Responsibilities:**

- Provide strategic recommendations to clients regarding IVD product development (quality, preclinical, and clinical) based on risk assessment in view of USA market clearance.
- Work in synergy with colleagues specialized in drug development to co-develop CDx products within the frame of Personalized Medicine
- Assist clients with strategic communications (e.g. product classification), preparation of meeting information- packages, and FDA interactions (face-to-face meetings, teleconferences, etc).
- Prepare regulatory submissions for clinical investigations (e.g. IDE), USA premarket approvals (PMAs), USA premarket notifications (510(k)), post-approval reports, annual reports, and device listings.
- Provide continuous client support for the regulatory maintenance of the marketed products (e.g. design review, process changes, labeling). Knowledge of IVD products advertising and promotion is a plus.
- Provide responses to any regulatory ad-hoc questions that clients might have.
- Contribute to Business Development activities, i.e. expand project portfolio, and enhance company visibility in the IVD and medical devices field.

**Requirements:**

- B.Sc. or M.Sc. degree in life or physical sciences, with more than 6 years of regulatory affairs experience within the IVD industry or medical device industry. Knowledge in molecular biology/biochemistry is a plus.
- Demonstrated ability to effectively present strategic regulatory information to Competent Authorities (e.g. pre-IDE meetings, interactions with the FDA).
- Sound understanding of the regulatory and Quality Assurance requirements as applicable to IVDs (e.g. Harmonized ISO 13485 standard) and of medical devices in general in the USA.
- Client and business development oriented with excellent communication skills; able to manage project budgets; negotiation, technical and regulatory writing skills.
- Knowledge of regulatory requirements in other regulatory regions is a plus (e.g. EU, Asia)
- Proactive, highly motivated, flexible person, enthusiastic approach to team working and able to work in a multicultural environment.
- Prior manager experience, with direct supervision responsibilities.

**Please email your CV and cover letter at [hr@voisinconsulting.com](mailto:hr@voisinconsulting.com)**