**Associate Director/Director, Regulatory Affairs, Medical Device**

**Job summary**

Genescience is a focused healthcare company and a leader in endocrine and growth disorders. We are expanding our research unit in therapy areas of endocrine disorders and chronic metabolic diseases with the mission to discover novel treatments for patients inflicted with those disorders.

The Associated Director or Director, Regulatory Affairs, Medical Devices, would be part of GenSci Global Regulatory Affairs team to provide regulatory guidance and oversight to ensure compliance with internal SOPs, US FDA, and international regulatory laws, standards, and regulations. Participate in regulatory intelligence gathering activities and maintain knowledge of US, EU and ROW device regulatory requirements.

**Essential job functions and duties**

* Provide regulatory expertise and guidance on regulations and requirements. Strategically interpret, plan, and communicate requirements to ensure regulatory authorizations are obtained
* Represent Global Regulatory Affairs on relevant program teams and subteams providing solid regulatory guidance (e.g., protocol reviews, report reviews, study manuals, development plans) to support efficient investigational device development
* Interact with key personnel in regulatory agencies to ensure the review and approval of development plans, the timely resolution of issues, and the approval of applications
* Write device-related regulatory documents to support regulatory agency submissions in collaboration with medical device vendors
* Effectively plan, organize, and conduct formal meetings/teleconferences with regulatory agencies for designated programs
* Develop and maintain global regulatory strategy for device during product life cycle. Conduct regulatory intelligence to identify country specific regulations and requirements for Inovio’s products including product labeling
* Review and approve data and documentation required for medical device or device pharmaceutical combination product regulatory submissions. Participate in cross-functional clinical study teams
* Provide input, review and recommendations for device design inputs & outputs, verifications and validations.
* Oversee organization and compilation of device regulatory submissions and other correspondence to US and international regulatory.
* Manage work through external consultants as needed to maintain throughput
* Maintain up-to-date knowledge of the data, information, and formats required for inclusion in these applications
* Participate in internal and external quality system audits. Collaborate with GenSci’s Quality Assurance and Engineering groups for maintaining compliance with applicable regulatory standards (e.g. FDA, MDR, ISO 13485 & ISO 14971)

**Minimum requirements**

* Bachelor/Master’s degree in engineering or a related area required
* A minimum of 10 years in regulatory affairs with a minimum of 5 years in medical devices
* Experience in drug-led combination products, 510(k), PMA, and/or CE Mark submissions desirable
* Knowledge of device global regulatory requirements required such as 21 CFR 820, 21 CFR 4, 21 CFR 3.2, and ISO 13485
* Experience and knowledge of the relevant current requirements for medical device or combination product submissions to US FDA and prior interaction or exposure with other key regulatory authorities (e.g. EU Notified Bodies, etc.)
* Excellent oral and written communication, interpersonal and organizational skills, and attention to detail
* Ability to interact effectively with management and prioritize multiple projects
* Technical proficiency, effective problem solving and critical thinking skills
* Ability to work in a team environment
* Strong project management skills and drive for excellence

\*This position is fully remote in US.