Interested Parties should contact:
Keith Ryan kryan@geneousbiomedical.com
508 359 4120

Position: Director / Vice President, Regulatory Affairs Business
Location: Boston area or remotely based

Who We Are

Our Client is creating a new category of *in vitro* diagnostics focused on decentralized, near-patient and point-of-care testing for everyone. The Company's proprietary technology platform positions them in the vanguard of the rapidly evolving and increasingly patient-directed landscape of consumer diagnostics, where convenience, rapid "test and treat," and portability are becoming critical to success. They aim to meet patients where they are and improve patient outcomes by arming healthcare professionals with an intuitive, rapid and cost-effective solution for on-demand diagnosis of infectious diseases.

Where we are going

Besides improving the in-clinic experience, they are striving to reach patients from the comfort of their home and provide a straightforward and secure path towards sexually transmitted infection detection, prevention, and treatment. They are striving to create a product that will make managing your sexual health easy, celebrated, and normalized.

The **Director** [Vice President] **of Regulatory Affairs and Quality Assurance** will report directly to the Chief Operating Officer and will have responsibility for leading all aspects of regulatory and quality strategy development and ensuring all related activities are performed in accordance with FDA, EU and other applicable regulatory standards and guidelines. This position will play a critical role in determining, implementing and maintaining an internal infrastructure that is compliant with the QSR, 21 CFR Part 820.

This position has regulatory and quality enforcement responsibilities and as such requires the highest level of professionalism best manifested in leading by example and supporting a culture of inclusion and transparency. The individual must be an excellent teacher so as to instruct team members at all levels of the company on compliance with international regulations.

Responsibilities

- Understands the concepts of least burdensome compliance with regulations as balanced with the need for design, manufacturing, distribution and commercial controls.
- Acts as the Management Representative in compliance with ISO 13485 5.5.2 and 21 CFR Part 820.20
- Leads a value-added auditing program designed to audit regulatory compliance within a framework of relative importance
- Provides strategic regulatory leadership and execution for all development projects, including but not limited to, overall global regulatory strategy, regulatory requirements for registration in domestic and international markets, and regulatory risk assessments and mitigation for all Company programs.
- Effectively leads the preparation and submission of marketing approval applications (510(k)s, CE marking, international licenses, etc.)

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- Lead all regulatory communications with FDA and interactions with EU competent authorities to ensure alignment with present CE marking Self Certification and future EU IVD Directives.
- Maintains excellent relationships with regulatory agencies, subcontractors, and providers of clinical studies.
- Ensures that all the manufacturing and quality programs relevant to the manufacturing of the Company products, such as process and manufacturing development, validation plans, production, release, and labeling, are appropriately structured to meet US, European, and other regulatory requirements.
- Builds partnerships with senior key stakeholders from other functions to ensure that strategic business goals are met through sharing of knowledge, expertise, and relevant information.
- Provides guidance and information to the Senior Management Team on emerging trends, regulations, and health authority guidelines to ensure use of the desired regulatory strategies.
- Provides counsel, training and interpretation of FDA and other regulatory requirements to all appropriate staff members and where appropriate to other teams and individuals. Cultivates an atmosphere of transparency and problem-solving that encourages requests for advice and input by company staff.
- Interprets and communicates regulatory expectations to internal and external stakeholders (including partners, supply chain, service providers, CROs, consultants, and contractors) in order to execute program objectives in compliance with applicable regulations.
- Promote the development of a company-wide understanding of the key elements related to quality and regulatory compliance requirements.
- Effectively manage the preparation and submission of marketing approval applications (510(k)s, CE Marking, Design Dossiers, International Licenses, etc.).
- Develop and execute quality design and quality assurance strategy for new product development and sustaining business activities.

Professional Qualifications

- 7-10 years+ of experience in clinical *in-vitro* diagnostic regulations, including successful pre-market submissions for domestic and international markets. Experience with molecular diagnostics a plus.
- Proven record of leadership and managing regulatory/quality organizations with global responsibility and establishing long term strategic growth initiatives.
- Experience with all phases of the product development lifecycle, including concept, design, implementation, verification and validation activities necessary for product commercialization.
- Experienced in regulatory filings for US (510(k), IDE and PMA) and other key countries/regions.
- Current knowledge of US and international *in vitro* diagnostic regulations and guidelines.
- Demonstrated success in the development and implementation of facility quality management systems and assuring compliance to all applicable regulations.
- 'Creative thinker' with the ability to develop novel solutions to challenging problems.
- High level of personal and professional integrity and trustworthiness with strong work ethic and the ability to work independently with minimal direction.
- Excellent interpersonal and strong leadership skills; self-motivated and flexible to changing schedules.
- Willingness to regularly travel to our UK offices

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Individual Traits

- Thinks and humbly challenges
- Open to and encourages inquiry and debate; intellectually curious
- Gritty; resilient and determined
- Focuses on execution and outcomes, not on effort
- Team player