Job Description – Highland Circle Innovations (HCI)

Senior Regulatory Affairs Specialist

Position Description:
You will be a high contributing member of an entrepreneurial team that supports the design and development activities of new products within a medical device consultancy, Highland Circle Innovations (HCI). You will have the opportunity to lead a segment of clients in many diverse medical device and diagnostic fields including: fetal and maternal monitoring, brain patient care applications, adjunct tools to echocardiography, and more. You will help streamline and speed our time to market across multiple products in exciting emerging technology areas. As a member of the Highland Circle Innovations Regulatory Affairs team, you will be on the leading edge of creating meaningful impact to patients, physicians, and payors in a small, fast-paced and innovative environment.

Job Summary
The Senior Regulatory Affairs Specialist is responsible for leading premarket development activities for HCI and its portfolio of companies. This position will support the overall strategic direction for Regulatory Affairs and work collaboratively across multiple functions and external governing bodies to ensure HCI's products and services meet the needs of our patients and customers, as well as to remain compliant to global regulations. This role will collaborate with engineering and quality teams to lead regulatory submissions for HCI's clients.

The Senior Regulatory Affairs Specialist will report to the Director of Regulatory Affairs.

Duties & Responsibilities:
- Designs and implements regulatory strategies and provides oversight in support of submissions, device labeling and promotional materials
- Provides premarket support to introduce new products and supports existing products in the marketplace for a segment of Regulatory Affairs functions for several clients
- Leads projects and supports products across early-stage medical technology companies
- Works collaboratively with key internal stakeholders such as Research & Development, Clinical, Operations and Marketing
- Assesses and provides input into how industry-wide changes should be reflected in the planning process
- Maintains external visibility to new and changing regulatory trends and guidance as input to HCI's clients' strategies

Position Must Haves:
- BS or BA in relevant field
- Minimum 4 years of relevant medical device regulatory affairs experience
- Proven track record of leading or supporting FDA regulatory 510(k) clearances and/or approvals in an efficient manner
- An intimate understanding of Quality System Regulations (21 CFR 820), and 510(k) premarket notifications
- An understanding of the scientific, technical, manufacturing, marketing and regulatory processes involved in the development of a medical devices
- Excellent communication skills across all levels of the organization with the ability to effectively convey subject matter expertise, provide constructive recommendations and influence without authority
- Flexibility, persistence, passion, resourcefulness, a drive to succeed, and an entrepreneurial spirit
- Ability to excel in an ambiguous, fast-paced, dynamic environment with significant growth and change expected over the coming years

- Demonstrated proficiency in the following HCI core competencies:
    - Deliver Results with Integrity. Has a strong bias for action. Meets commitments and produces the right results at the right time. Behaves ethically in all situations. Is credible and trustworthy.
    - Customer Focus. Consistently recognizes current and anticipated future needs of internal and external customers and communicates them proactively.
    - Team Player. Creates an environment of collaboration and trust. Takes initiative to help others in order to accomplish team and company objectives.
    - Technical & Industry Knowledge. Demonstrates proficiency of technical and industry knowledge; keeps abreast of changes to remain knowledgeable.

Position Nice to Haves:

- RAC-Devices Certification
- MS or MA in relevant field
- Experience leading EU MDR readiness
- Familiarity with clinical affairs and clinical data analysis
- Familiarity with combination products

Physical Job Requirements:

The physical demands described within Position Description section within this job description are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions

Significant Work Activities: Continuous sitting for prolonged periods, Keyboard use (greater or equal to 75% of the workday)

Location: Twin Cities Metro Area, MN preferred. Open to remote applicants.

Travel: Yes, <10% of the time

Highland Circle Innovations is an Equal Opportunity Employer of Minorities/Women/Individuals with Disabilities/Protected Veterans.