Manager, Clinical and Regulatory Affairs

About us

We are innovators.

Nimble is advancing a new frontier in medicine by enabling a first in kind access to the gut microbiome with its novel fluid biopsy pill. This is a critical and multi-faceted leadership role in an early-stage company.

Role Summary

Reporting directly to the CEO, this is a growth role for a motivated and skilled individual.

Primary responsibilities are to 1) maintain and improve Nimble's Quality Management System (ISO 13485) as Quality Manager, 2) create and execute regulatory and clinical projects to ensure compliance and access to R&D partnerships worldwide. The position will be responsible for supporting product releases, which includes regulatory submissions, pre-market to post-market compliance to all applicable national and international standards.

The successful candidate will have demonstrated proficiency in at least one of quality, regulatory and/or clinical affairs, with an interest and aptitude to take on responsibilities in all three. The challenge will expand as the company grows. Personal strengths in risk-based decision making, and effective communications with internal and external stakeholders is a necessity.

Position start date on or before June 1, 2022.

Responsibilities

- Participate in corporate strategic planning: plan, develop, implement, and optimize the Company's global regulatory and quality strategy.
- Lead the development, implementation, and continuous improvement of quality management systems (QMS) as Quality Manager.
- Establish and implement regulatory strategies for the use of investigational devices in diverse jurisdictions
- Prepare, and submit international regulatory submissions as required.
- Oversee and/or serve as the key contact for the regulatory agencies on all issues arising out of the development, commercialization, and manufacturing of Nimble Products.
- Optimization of processes within Quality Assurance and Regulatory Affairs to ensure timely delivery of key deliverables.
- Determine governmental regulations affecting Company processes and assure the processes are complete and accurate to ensure company compliance.
- Review promotional materials for regulatory compliance. Provides regulatory approval of internal procedures and processes.
- Supports product recovery and/or recall activities.
- Responsible to set the quality assurance strategy and ensure compliance with all Quality standard requirements in all designated jurisdictions worldwide.
- Evaluate changes to controlled documents for impact on submissions and filing requirements, including providing a technical review of and approval for proposed changes and supporting documentation.
- Participate in the review of clinical protocols, clinical data and study reports in order to assure compliance and conveyance of key messaging throughout the regulatory submission process.

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- Lead the implementation of clinical projects ensuring the quality of clinical trials including compliance with study protocols, SOPs, GCP/ICH, and regulatory (Health Canada, FDA) requirements.
- Support day to day planning, execution, and reporting of studies investigating the use of the company's technologies.
- Develop and Manage Quality and Regulatory Affairs budgets.

Education:

- University degree at a Bachelor level or greater in relevant Science or Engineering Field
- Master's degree or Regulatory Affairs Certification (RAC) or Quality certification, preferred – not required

Experience:

- 3+ years of experience working in at least one of a Quality, Regulatory or Clinical Affairs role
- Working knowledge of medical device licensing and investigational use in Canada and the U.S. required, EU knowledge a preferred asset
- Working knowledge of the Quality Management System registration requirements of ISO13485
- Working knowledge of FDA Quality Systems Regulations, GMP's, ISO 13485, Medical Device Regulation EU 2017/745, Medical Device Directive 93/42/EEC, ISO regulations/standards, including ISO 13485, 10993, 14971, strongly preferred
- Experience with medical device product development; regulatory manufacturing device registrations, quality system, new product development, design controls.

Skills:

- Ability to communicate effectively at all levels of the organizations
- Confident, responsible, dependable, punctual, realistic, positive, flexible, efficient
- Highly results-oriented leader with superb project planning skills and ability to work in a dynamic environment with competing deadlines
- Excellent all-round customer/stakeholder focus
- Excellent documentation and organizational skills

Application Process

Apply Quick – interviews can start immediately and will continue until the position is filled.

Apply directly with a Cover Letter stating your interest and how previous experience can help you quickly learn the needed skills. **Send cover letter and resume to sabina@nimblesci.com**