Senior Regulatory Affairs Specialist

Third Pole is a growing cardiopulmonary therapeutics company working with world-class partners to develop unique and disruptive therapies that will have an immediate impact, saving lives on a global scale. Third Pole's first therapy is delivered via a tank-free, nitric oxide delivery system which offers a revolutionary solution enabling newborn babies, who currently lack access to this medicine, the ability to be treated.

In this role, you will apply your regulatory affairs experience to ensure our medical devices are safe and effective. You will work cross-functionally with R&D Engineering (Systems, Mechanical, Electrical, Software, Test, Core Technology), Quality, Clinical, Usability, Product Management, and Manufacturing. As a key participant in product development activities, you will be responsible for accurate timely submissions, amendments, supplements, and/or other regulatory correspondence.

Responsibilities

- Participate in new product development teams to clearly communicate new and existing regulatory requirements applicable to Third Pole products.
- Facilitate compliance with regulatory requirements by reviewing and approving documentation such as Change Controls, test protocols and reports, and device labeling.
- Develop and author regulatory submissions, including Investigational Device Exemptions (IDEs), Premarket Approval Applications (PMAs), Technical Documentation, Pre-Submissions, and various Supplements by:
    - Help determine effective regulatory strategies with regulatory affairs leadership.
    - Writing and reviewing high-quality regulatory documents.
    - Tracking regulatory submission activities to ensure timelines are met.
    - Coordinating responses to regulatory agencies as part of the submission and approval process.
    - Maintain product registrations/approvals and regulatory records.
- Assist in regulatory compliance activities, including but not limited to:
    - Write/update and review standard operating procedures, work instructions, templates, etc. for Quality Management System improvement activities
    - Prepare for and participate in regulatory audits/inspections (ISO 13485, MDR, and FDA).
    - Assist Quality with internal audits of the QMS.
    - Conduct trainings and/or communicate appropriate materials to enhance team/company knowledge of working in a regulated environment.
- Work closely with Clinical Operations and supporting CROs to ensure effective compliance for clinical trial activities.
- Maintain/submit facility registration, device listing, periodic reports, etc. per global requirements.
- Acquire and maintain current knowledge of applicable global regulatory requirements and trends and develop strategy and provide internal guidance related to such trends.
- Other duties as assigned.

Required Qualifications

- Bachelor's in Engineering or Science required; advanced degree preferred.
- 5+ years regulatory affairs with FDA / EU / international submissions for Class II or III medical devices required.

- Current and working knowledge of FDA 21 CFR 820, ISO 13485, and EU MDR.
- Experience reviewing technical and design specifications and working knowledge of medical device design controls.
- Previous experience with authoring and reviewing regulatory submissions.
- Experience with ISO 14971, IEC 60601, IEC 62366, and IEC 62304.
- Strong technical writing skills that result in clear, concise, comprehensive, and high-quality regulatory submissions.
- Demonstrated attention to detail.
- Excellent verbal communication, presentation, organizational, and project management skills.
- Experience with Electronic Document Management Systems (EDMS); Orcanos preferred.
- Proficiency with MS Office applications (Excel, Word, PowerPoint, Visio) and Adobe Acrobat.
- Ability to remain focused while working in a fast-paced, dynamic environment.

Preferred Qualifications

- Experience in patient monitor systems, hospital-based products, software-driven devices, or respiratory products.
- Experience with early stage product (clinical phase) development.
- Familiarity with medical terminology.

Equal Opportunity Employer

Third Pole, Inc. provides equal employment opportunity (EEO) to all persons regardless of age, color, national origin, citizenship status, physical or mental disability, race, religion, creed, gender, sex, sexual orientation, gender identity and/or expression, genetic information, marital status, status with regard to public assistance, veteran status, or any other characteristic protected by federal, state, or local law.

Reasonable Accommodations

The job summary, responsibilities and requirements listed above are intended to describe the general nature and level of work being performed by employees assigned to this position, but they are not an exhaustive list of all the responsibilities and skills required of this position. Reasonable accommodations may be made for any part of the application or interview process, and to enable qualified individuals with a medical condition or disability to perform the essential functions.