THIRD POLE

Quality Manager, Boston MA

Third Pole, Inc. is a growing cardiopulmonary therapeutics company that is developing a unique technology to make inhaled nitric oxide (NO) from air. Inhaled NO is an effective tool, but tanks of NO are not widely accessible for treating heart and lung diseases worldwide. Our tank-less product will offer a disruptive solution which will allow us easy entry to both US and Global markets. Our product will be so simple to use that babies who currently lack access to this medicine will soon be treated; saving lives in China, India, Kenya and worldwide.

The Quality Manager will establish and provide quality system leadership in the areas of the Quality System, the CAPA Program, quality training, audit management, oversee document control, and to ensure company compliance to ISO 13485, FDA CFR and other applicable regulations and standards. In addition, the Quality Manager will also help in generating and maintaining SOPs, prepare management review materials, identify and track metrics

RESPONSIBILITIES:

- Develop and maintain the Quality System and quality metrics.
- Responsible for establishing objectives, timelines, milestones and project priorities based on compliance risk assessment and business prioritization in a CE, FDA, QMS, ISO 13485 environment.
- Ensure training of company personnel is in compliance with the Quality Manual and maintain training records.
- Identify Quality System deficiencies through internal audits.
- Participate in the preparation and execution of management reviews
- Establish strategic direction for the Corrective and Preventive Action program; including processing, monitoring, reporting and resolving CAPA improvements.
- Lead in submissions of FDA and CE products.
- Manages audits for (Regulatory Agencies, Notified Bodies, and Internal Audits)
- Communicate with regulatory authorities, as needed.
- Monitor activities/publications of FDA and international regulatory bodies to identify and respond to new or revised regulatory requirements. Guides and coaches process owners in the development of compliant processes and procedures.
- Maintain Establishment Registrations, Device Listings, and Import/Export filings, as needed.
- Review all V&V protocols to ensure they meet FDA regulations and guidance and are in compliance with ISO 13485.
- Vigilance and MDR reporting, as needed.
- May supervise others.

QUALIFICATIONS:

- Bachelor's degree required, master's preferred.
- Minimum of 7 years' experience in quality system management in the medical device industry required.
- A thorough knowledge of national and international regulations applicable to medical devices including; Quality System Regulations, 21 CFR 820, 21CFR 803 and 804 (MDR regulations), Canadian Medical Device Regulations, ISO 14971, ISO 13485, and MDD 93/42/EEC
- This position requires the ability to identify, build and maintain the strategic direction of the quality assurance system.
- Strong verbal, written and organizational skills.
- Demonstrate a strong "business partner" approach and attitude providing creative and innovative solutions that meet quality standards.
- Working knowledge of HIPAA, IRB, IDE, CE Mark, 510(k) and PMA submission requirements.
- Pre-market regulatory affairs experience preferred
- Experience leading internal, supplier and regulatory body audits
- Skill in multiple computer based tools and software programs such as Word, PowerPoint, Excel, Visio, MS Project etc.
- Experience in OWNING the ISO Certification process before is required.

Continue your career while saving babies around the world with our brilliant technology!

For immediate and confidential consideration send your resume to careers@pole3.com