EXHIBIT A - JOB DESCRIPTION

Job Title: Director of Regulatory Affairs and Quality
Department: Product
Reports to: CEO
Position Type: Full Time Non-Exempt

PRIORITY RESPONSIBILITY

We are seeking an experienced Regulatory Affairs and Quality Manager with expertise in **ISO 13485** to lead and manage our regulatory compliance and quality management systems. The ideal candidate will play a pivotal role in ensuring product compliance with applicable regulations and standards, managing audits, and driving continuous improvement initiatives. This position involves collaboration across teams to support product development, manufacturing, and market access activities globally.
We prefer candidates in the Bozeman, MT or Las Vegas/Henderson, NV area. We would also be open to remote positions.

ESSENTIAL DUTIES

1. **Compliance & Submissions:**
    - Develop and implement strategies for obtaining regulatory approvals for medical devices in global markets, including CE marking under the EU MDR/IVDR, FDA 510(k) submissions, and other regional requirements.
    - Maintain current knowledge of global regulatory requirements, standards, and guidelines, including ISO 13485, FDA QSR, and MDSAP.
    - Prepare and submit technical documentation, product registration dossiers, and regulatory filings.
2. **Communication:**
    - Act as the primary liaison with regulatory agencies and notified bodies, managing audits, inspections, and inquiries.
    - Provide guidance to cross-functional teams on regulatory requirements during product development, changes, and post-market surveillance.
3. **Risk Management:**
    - Oversee product risk assessments and ensure compliance with ISO 14971 (Risk Management for Medical Devices).
4. **Misc cross functional assignments** such as project management, marketing support and operational tasks.

Quality Management:

1. **ISO 13485 Oversight:**
    - Develop, implement, and maintain the Quality Management System (QMS) in compliance with ISO 13485 and other applicable standards.
    - Lead internal and external audits, including MDSAP and notified body audits, ensuring readiness and successful outcomes.
2. **CAPA Management:**

- Oversee Corrective and Preventive Actions (CAPA), ensuring timely identification and resolution of non-conformities.
- Analyze quality metrics to identify trends and drive continuous improvement initiatives.

3. **Supplier & Manufacturing Quality:**
   - Manage supplier qualification, audits, and performance evaluations to ensure compliance with quality standards.
   - Collaborate with manufacturing teams to establish robust quality controls and processes.
4. **Documentation & Training:**
   - Maintain and update QMS documentation, including procedures, work instructions, and records.
   - Develop and deliver training programs to ensure organizational understanding of regulatory and quality requirements.

QUALIFICATIONS

1. ***Education:***
   - *PhD in a relevant field (e.g., Life Sciences, Engineering, Regulatory Affairs, or Quality Management).*
   - *Current ISO certifications are a plus.*
2. ***Experience:***
   - *Minimum of 3–5 years of experience in Regulatory Affairs and Quality Management in the medical device industry.*
   - *Proven expertise in ISO 13485 implementation and maintenance.*
   - *Experience with CE marking, FDA submissions, and global regulatory frameworks.*
3. ***Skills:***
   - *Strong knowledge of medical device standards (ISO 13485, ISO 14971) and applicable regulations (EU MDR/IVDR, FDA QSR).*
   - *Exceptional project management, analytical, and organizational skills.*
   - *Strong interpersonal and communication skills, with the ability to lead cross-functional teams.*
   - *Proficiency in quality management software and document control systems.*
4. ***Certifications (Preferred):***
   - *Certified Quality Auditor (CQA) certification.*

INTERESTED?

If you are interested in a challenging and rewarding position with an exciting company, please send your resume and letter of interest to personnel@goldenhelix.com. Please note any prospects will be contacted from a goldenhelix.com domain email address.