Rare opportunity to join high energy healthcare innovation company focused on developing infection management products, medical devices, and OTC products. We are rapidly advancing innovative technologies and are looking for like-minded candidates to help bring real products to the market.

Parvizi Surgical Innovation, LLC was founded on the core principals of improving patient outcomes with novel and innovative technologies that can often affect the patient, family, the provider, and the healthcare system. PSI focuses on research & development, product testing & refinement, manufacturing, regulatory activities and clinical trials while securing intellectual property (patents, trademarks, and copyrights) for pre-clinical and clinical use.

Our group is seeking a highly motivated candidate for the position of:
Project Manager
Location: Philadelphia

Reporting to senior management, you will independently lead, manage and execute within a range of projects leading directly to real innovations.

The job requirement will focus on: managing development of several over-the-counter (OTC) products, including developing project plans, managing relationships with accounts, and overseeing all aspects of the project. Secondarily, establishing QMS systems, ensuring compliance to the overall quality management system, in some cases developing QMS systems, coordinating with manager on scope and deliverables. You will also be accountable for QMS project plans, working with internal and external engineers and quality team, and aligning with manufacturing partners. Drive continuous improvement.

You may also work with our business partners in defining and monitoring project requirements.

Main tasks:

- Manage the execution of engineering projects, including coordination with manufacturing partners and other vendors involved in the project
- Managing budget, schedule and communicating updates to key stakeholders within the project
- Ensure QMS compliance of the regulatory standards and requirements.
- Manage all phases of the Design History File for product development while working closely with project manager and R&D team.
- Drive all functions around document storage, record keeping and implementing protocols and procedure.
- Identify and implement improvement opportunities to increase the efficiency and effectiveness of the QMS and provide leadership to projects.
- Contribute to the development, maintenance, and improvements of policies and procedures.
- Communicate with notified bodies and authorities.
- Manage internal and external audits.
- Liasson between all members of the project management team, vendors, and consultants.
- Responsible for identifying resource needs and developing schedules to ensure timely project completion.
- Coordinate QMS activities and plans to support the achievement of project milestones.
- Responsible for improving team performance by establishing quality objectives and maintaining metrics.
- Define organizational plans, requirements and goals.
- Meet budgetary objectives and make adjustments based on financial analysis.

- Coordinate with internal team members, partners, vendors and suppliers to maintain a high level of communication to support accurate reporting.
- Other duties as assigned.

Qualifications

Education & Experience and Recommendations:

- Bachelor's degree in engineering, Business, or related field
- 3-5 years minimum experience of QMS management and implementation in the medical device and/or over-the-counter (OTC) industry preferred.
- Understanding of Quality Management Systems, FDA Guidelines, OTC, ISO 13485, and 21 CFR 820 & 821, 21 CFR 330, FDA Monographs
- Proven track record in managing quality system requirements.
- Greenlight Guru experience helpful but not required.

PSI offers:

- An opportunity to participate and grow in the field of medical device and healthcare
- An inspiring work environment
- Challenging projects with impactful outcomes
- An opportunity for professional development

Please contact us: contact@parvizisurgical.com