SHURIG SOLUTIONS INC.

Vertos MEDICAL

Director of R & D

Job Location – Aliso Viejo, CA

Job Summary:

Lead and manage product development cycles including ideation, technology, and product development/ advancement through team efforts, coordinating cross-functional partnerships, and ensuring team understanding and accountability to project investments and timelines.

Duties and Responsibilities:

- Assume complete responsibility of projects to ensure on-time, on budget, per plan delivery of quality products including development, product verification, and validation testing. The leadership includes overall design, requirement development, design for manufacturing, and test methods.
- Develop, manage, and maintain up-to-date project timelines inclusive of all critical milestones, key interdependencies and resource constraints, while applying appropriate project scheduling techniques.
- Guide project team activities to meet project and business objectives including approval of project recommendations through governance; drive team accountability for deliverables and ensure projects meet milestones.
- Lead cross-functional team.
- Create Design History file that complies with FDA and ISO medical device requirements.
- Define scope and ensure stakeholder alignment, resource and risk management, project leadership, team development and communication.
- Proactively identify and escalate risks and issues to relevant stakeholders; lead development and delivery of tactical and achievable mitigation and contingency planning.
- Deliver transparent, timely, and effective verbal and written

communication to teams, stakeholders, and appropriate levels of the organization.
- Excel at project facilitation, collaboration, attention to detail.
- Identify and recommend the best enterprise business proposition.
- Evaluate market reactions to existing products to ensure the timely adjustment of development strategy and plans to meet changing market and competitive conditions.
- Interact with external customers to understand ongoing market trends and customer needs.
- Work closely with Regulatory Affairs and Quality Assurance to ensure that the development of products meets and/or exceeds both company and Federal quality standards.
- Evaluate the clinical functionality and reliability of new designs.
- Develop staffing plan, budget, and manage priorities throughout the evolution of development exercises.
- Maintain and increase professional and technical knowledge by on-the-job training, attending educational workshops, reviewing professional publications, establishing personal networks, and participating in professional societies.
- Support compliance with the company quality standards, FDA regulations and guidance, applicable EU Medical Device directives, applicable ISO standards, and other pertinent country specific medical regulatory requirements.
- Perform special projects and other duties as assigned.

Education & Experience:

Required

- Bachelor's degree in engineering.
- A minimum of ten years’ relevant experience or advanced degree with a minimum of eight years’ relevant experience, both including a minimum of three years’ experience managing people.
- Experience in managing Class II device development programs in

the medical device space with knowledge of regulatory and quality requirements.
- Experience in product development from early feasibility to commercialization and in managing complex tasks and delivering innovative solutions.
- Strong multidisciplinary background with comprehensive knowledge of systems engineering.
- Strong understanding of quality systems, regulatory requirements, development, and manufacturing processes.

Bonus

- Direct prior experience with spine products inclusive of design as well as test protocol experience.
- Experience working with key opinion leaders in the field to identify market requirements, industry, and regulatory partners.
- Six Sigma and Lean knowledge.
- Knowledge of financial metrics and interactions.

SKILLS, ABILITIES, and CHARACTERISTICS

- Strong project management skills.
- Strong technical aptitude and execution skills with a demonstrated ability to test product concepts that are clinically usable.
- Display broad perspective and effective judgment, demonstrate well-reasoned problem solving and decision-making.
- Build a shared vision; inspire others to action; set clear direction; establish plans consistent with that direction.
- Solid past performance as a project manager with a demonstrated track record of successfully bringing medical devices to clinical investigation and ultimately market approval.
- Ability to work and excel within a fast paced, dynamic, and constantly changing work environment.
- Ability to interact professionally with all organizational levels and proactively escalate issues to appropriate levels of management in

the organization.
- Ability to conduct business and technical briefings for senior and top management and for external representatives.
- Ability to support multiple projects and balance priorities.
- Strong interpersonal skills and people management skills.
- Strong oral/written communication skills.
- Tech savvy: proficiency in Microsoft Office applications and in mobile/cloud resources including CRM software (preferably Salesforce) and ERP software (preferably NetSuite); comfortable learning new technical systems as needed such as Box, Zoom, Slack, and Concur.

PHYSICAL REQUIREMENTS/WORK ENVIRONMENT

- **Travel (Distributed Workforce)** – Approximately 25% of time will be spent traveling for team meetings, conferences, labs, and trainings.
- **Physical Demand** – While performing the duties of this job, the employee is regularly required to stand, walk, and sit for extended periods of time. Some of the time standing will include wearing radiation safety equipment (lead aprons, thyroid shield, radiation badge, etc.). Physical effort required by handling objects of up to 25 pounds frequently. Specific vision abilities required by this job include close vision, distance vision, depth perception, and ability to adjust focus in relation to travel and operating a personal computer. The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
- **Mental Demand** – Moderate to high degree of concentration due to volume, complexity, and/or "pressure" of work. Ability to make critical thinking skills decisions under pressure.
- **Work Environment** –
    - Potential exposure to bloodborne pathogens,

pharmaceuticals, chemicals, needles, and sharps, and radiation (from x-ray

- When working in a home office environment, a dedicated office with minimal distractions which assures maximum privacy of computer screens to protect confidential and sensitive information is required; highspeed internet connectivity is required to work effectively.