COLLAGEN SOLUTIONS
MATERIALS FOR LIFE

JOB DESCRIPTION

POSITION TITLE: Principal Engineer, Structural Heart
DEPARTMENT: Research and Development
POSITION REPORTS TO: VP of Research and Development
FLSA: Exempt

POSITION PURPOSE

The Principal Engineer works within the R&D department to drive internal & contract product development & research programs. This position is a key role within the R&D organization ensuring innovative and quality products are delivered in a timely manner while maintaining compliance with industry standards and regulations. They will be seen as a recognized leader while exhibiting the company's values of teamwork, customer focus, accountability, and integrity.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Champion new product development projects: researching, developing, and securing regulatory approval for new regenerative medicine products.
- Actively engage and collaborate on global cross functional product development teams.
- Medical Device Design Control and Risk Management.
- Project management as necessary.
- Plan, schedule and coordinate project tasks and activities.
- Utilize structured problem-solving approaches to resolve design investigations during development.
- Provide mentorship.
- Conceptualize new devices, techniques, and technologies using material knowledge and innovative design.
- Prepare documentation in accordance with relevant internal SOPs.
- Work closely with product development team to establish product development goals while ensuring market compatibility.
- Grow the company's IP & patent portfolio through strategic internal research.
- Ability to interface with physicians on product design and use.
- Author engineering reports and presentations as required to document and communicate results.
- Create prototypes and conduct product testing, as necessary.
- Performs preclinical needs assessments.
- Experience with 3D modeling software (e.g. – Solidworks).
- Ensure compliance with regulatory and industry standards (FDA, MDD/MDR, ISO, ASTM, etc.) as appropriate.
- Support sustaining and process engineering efforts during process scale-up and manufacturing improvement initiatives.
- Contribute to and maintain compliance with company's ISO 13485 Quality System.
- Technical team member for non-conformances, deviations, CAPAs, and root cause investigations.
- Stay current with industry trends, emerging technologies, and best practices in biomedical engineering, tissue-related fields and structural heart market.
- Maintain laboratory notebooks.
- Maintain a safe work environment.
- Other duties as reasonably assigned by the management team.

QUALIFICATIONS

- Minimum bachelor's degree in Material Science, Bioengineering, Chemistry, or related technical discipline. Advanced degree preferred.
- 10+ years of medical device and design control experience.
- Extensive knowledge of the industry and market conditions, specifically collagen, tissue and other related biomaterials and contract development/manufacturing.
- Experience in tissue engineering and biomaterials is a plus.
- Experience designing and testing cardiovascular implants such as transcatheter and surgical heart valves including:
    - Tissue selection
    - Leaflet design
    - Fabric integration
    - ISO 5840 testing
        - BDC and ViVitro testing equipment
    - Tissue Fixation
    - Chemical Sterilization

KNOWLEDGE & SKILLS

- Project management experience a plus.
- Working knowledge of laboratory prototyping, safety precautions and protocols for safe handling and the disposal of hazardous agents, re-agents, chemicals, and materials.
- Thorough understanding of medical device industry. Working knowledge of other related disciplines.
- Working knowledge of Design for Six Sigma, Risk Management techniques, Statistical Analysis methods, and Design of Experiments.
- Ability to travel as needed (<20%) within the US and globally.
- Exceptional organizational, communication (verbal and written) and interpersonal skills.
- Work under minimal supervision.
- Attention to detail, effective problem solving and decision-making skills.
- Knowledge of MS project software, Outlook, MS Excel, MS Word, MS PowerPoint.

INTENT AND FUNCTION OF JOB DESCRIPTIONS

Job descriptions assist organizations in ensuring that the hiring process is fairly administered and that qualified employees are selected. They are also essential to an effective appraisal system and related promotion, transfer, layoff, and termination decisions.

All descriptions have been reviewed to ensure that only essential functions and basic duties have been included. Peripheral tasks, only incidentally related to each position, have been excluded. Requirements, skills, and abilities included have been determined to be the minimal standards required to successfully perform the positions. In no instance, however, should the duties, responsibilities, and requirements delineated be interpreted as all-inclusive. Additional functions and requirements may be assigned by supervisors as deemed appropriate.

Job descriptions are not intended as and do not create employment contracts. The organization maintains its status as an at-will employer. Employees can be terminated for any reason not prohibited by law.