COLLAGEN SOLUTIONS
MATERIALS FOR LIFE

JOB DESCRIPTION

POSITION TITLE: Sr. Manufacturing Engineer
DEPARTMENT: Operations
POSITION REPORTS TO: Operations Manager
FLSA: Exempt

POSITION PURPOSE

The Sr. Manufacturing Engineer will be based out of the Collagen Solutions headquarters in Eden Prairie, MN and will support a global biomaterial med tech organization. The role is a key member of the engineering team reporting to the Operations Manager. The Senior Manufacturing Engineer is a primary point of contact for manufacturing projects from new product introductions to continuous improvement projects. The Sr. Manufacturing Engineer integrates with other departments on multiple manufacturing projects ensuring that they run to budget and within timelines. This role supports Production, EHS, Operational Excellence and quality functions to ensure coordinated manufacturing of products.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Supports active manufacturing with a focus on continuous improvement projects and operational excellence.
- Coordinate internal resources and third parties/vendors to ensure execution of projects.
- Ensure that all projects are delivered on time, within scope and within budget.
- Developing project scopes and objectives, involving all relevant stakeholders and ensuring technical feasibility.
- Develop detailed project plans to track progress.
- Measure project performance using appropriate systems, tools and techniques.
- Report and escalate to management as needed.
- Manage the relationship with the client and all stakeholders.
- Perform risk management to minimize project risks.
- Establish and maintain relationships with third parties/vendors.
- Create and maintain comprehensive project documentation.
- Present to the business and key stakeholders as appropriate.
- Liaising with the Commercial and R&D teams as required, providing information for proposal development
- Actively support timely closure of CAPAs, Complaint & audit actions.
- Ensure effective engineering disciplines are followed to deliver launches of new products that can be reliably & repeatedly manufactured.
- Identify potential capacity and operation efficiency opportunities.
- Ensure all activities are performed in accordance with relevant regulations or requirements.
- Any other duties as requested by Senior Management.

QUALIFICATIONS

- Bachelor's degree in engineering required.
- 4+ years of medical device industry/med tech engineering experience required.
- Design control/process validation experience required.
- Thorough understanding of Design for Six Sigma, Risk Management techniques, Statistical Analysis methods, and Design of Experiments required.

- Advanced degree in technical discipline preferred.
- Experience with transcatheter heart valve manufacturing and/or biomaterials preferred.

KNOWLEDGE & SKILLS

- Demonstrated mastery level knowledge with:
  - Design controls.
  - Process validation.
  - Equipment design and procurement.
  - Safety precautions and protocols for safe handling and the disposal of hazardous agents, re-agents, chemicals and materials.
  - Knowledge of effective engineering problem solving tools.
  - QMS change control.
- Works independently within established procedures associated with the specific job function.
- Must be able to adjust to shifting and sometimes unexpected priorities and new responsibilities.
- Exceptional organizational, communication (verbal and written) and interpersonal skills.
- Ability to lift and/or carry 50 lbs.

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.