



JOB DESCRIPTION

EXEMPT NON-EXEMPT

POSITION TITLE: Sr. Process Engineer

DEPARTMENT: Operations

APPROVED BY:

DIVISION: Collagen Solutions (US)

DATE: 06/03/2022

REPORTING RELATIONSHIPS

POSITION REPORTS TO: Ross Kohrs, Director of US Operations

POSITIONS SUPERVISED: 0 (Future growth opportunities)

POSITION PURPOSE

The Sr. Process Engineer will be based out of the Collagen Solutions headquarters in Eden Prairie, MN and will support a global med tech organization with offices in Scotland and New Zealand. The role is a key member of the engineering team reporting to the Director of Operations. The Senior Process Engineer is the point of contact for all matters relating to equipment and projects from new product introductions to improvement projects. Integrates with other departments to deliver on time and in budget performance in project and equipment areas. Manage multiple NPI projects ensuring that they run to budget and timelines with agreed project milestones communicating with all relevant parties both internally and externally. Supports Production, EHS, Operational Excellence and quality functions to ensure coordinated introduction of products and equipment. Work closely with site departments to develop efficiency and capacity improvement projects.

ESSENTIAL FUNCTIONS AND BASIC DUTIES

- Work on both new process / product introductions as well as continuous improvement projects
 - Coordinate internal resources and third parties/vendors for the flawless 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 a detailed project plan 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
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QUALIFICATIONS

EDUCATION/CERTIFICATION:

- Minimum bachelor's degree in Biomedical Engineering, Chemical Engineering, or related technical discipline. Advanced degree preferred

REQUIRED KNOWLEDGE:

- Demonstrated high level knowledge with:
 - Tissue engineering, biomaterials and/or polymers
 - Design controls
 - Process validation
 - Equipment design and procurement
 - Safety precautions and protocols for safe handling and the disposal of hazardous agents, reagents, chemicals and materials
 - Knowledge of effective engineering problem solving tools
 - QMS change control

EXPERIENCE REQUIRED:

- 4+ years of medical device industry/med tech experience
- Design control/process validation experience
- Thorough understanding of Design for Six Sigma, Risk Management techniques, Statistical Analysis methods, and Design of Experiments. Able to apply techniques and independently interpret results
- Experience in tissue engineering and biomaterials is a plus

SKILLS ABILITIES:

- 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.

OTHER REQUIREMENTS

PHYSICAL STRENGTH: Ability to lift and/or carry 50 lbs

LANGUAGE ABILITY: Proficiency in English

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.