Job Title: Sr. Engineer/Engineer III – (Office-based, Eden Prairie, MN)

Collagen Solutions is a global leader in collagen-based biomaterials supply and development for use in research and diagnostics, medical devices, and regenerative medicine. We are an exciting fast-paced growth company, wholly owned by Rosen's Diversified Inc's Life Sciences Division and are looking for high caliber team members passionate about our vision:

To be the industry's first choice for regenerative biomaterials.

The Sr. Engineer, Research and Development works within the U.S. based R&D function, to support & execute internal and contract product development projects. 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.

Essential Functions:

- 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***
    - Independently draft/author all typical design control documentation in accordance with relevant internal SOPs such as: trace matrices, design verification plans and reports, risk documentation, design validation plans and reports, usability reports, final product labeling (including IFUs).
- Independently lead interactions with external vendors such as test labs (e.g. biocompatibility, animal study, and analytical) and suppliers.
- Independently author engineering reports and presentations as required to document and communicate findings.
- Independently research, develop and formulate new products/prototypes
- Independently design, execute, compile data and draw conclusions for complex experimentation
- Assist with clinical/user needs assessments
- Fully knowledgeable of the clinical aspects of the product(s) to be developed, including: disease or anatomical malady, competitive product landscape and unmet needs of the current state of the art treatment(s)
- Assist with intellectual property searches and evaluations
- 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
- Maintain laboratory notebooks
- Maintain a safe work environment
- May mentor or supervise less experienced engineers, interns and co-ops
- Other duties as reasonably assigned by the management team

NOTE: This description is not intended to be all-inclusive. An employee may perform other related duties to meet the ongoing needs of the organization; these duties are considered marginal.

Requirements:

- Minimum bachelor's degree in Material Science, Bioengineering, Chemistry, or related technical discipline. Master's degree preferred
- 4+ years of medical device and **design control** experience
- Demonstrated mastery level knowledge with:
    - Tissue engineering, biomaterials and polymers
    - Design controls
    - Risk management and creating risk analyses
    - Laboratory prototyping
    - 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
- 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
- Ability to travel as needed (<20%) within the US and globally.
- Exceptional organizational, communication (verbal and written) and interpersonal skills.
- Works independently with general direction and minimal supervision
- Attention to detail, effective problem solving and decision making skills.
- Knowledge of MS project software, Outlook, MS Excel, MS Word, MS PowerPoint

Notice to Search Firms: We are not seeking assistance or accepting unsolicited resumes from search firms. We will not pay any placement, referral or other fees to any search firms unless we have agreed otherwise in a valid, written agreement.

Collagen Solutions, Inc. is an Equal Employment Opportunity / Affirmative Action Employer. *All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, veteran status, or any other legally protected status. Applicants with a disability who require a reasonable accommodation for any part of the application or hiring process can contact Human Resources at the location(s) where you are applying. Collagen Solutions, Inc. will not discriminate against applicants who inquire about, disclose or discuss their compensation or that of other applicants. Collagen Solutions, Inc. participates in the E-Verify program in certain locations as required by law.*