

Job Description: Manager, Research and Development

Collagen Solutions is a global leader in collagen-based biomaterials supply and development for use in regenerative medicine and medical devices. We are an exciting fast-paced growth company, looking for high caliber team members passionate about our vision:

To be the industry's first choice for regenerative biomaterials

The Manager, Research and Development works within R&D function to support & execute internal & contract product development & research 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:

- This position reports to the Vice President, R&D
- Champion, project manage and ensure completion of research and product development projects: research, develop and secure 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**
- Supervise, develop, train and mentor R&D staff
- Partner closely with commercial team to assess and support customer enquiries, ensure early technical understanding, and align development capabilities with client goals.
- Grow the company's IP & patent portfolio through strategic internal research
- Contribute to and maintain compliance with company's ISO 13485 Quality System
- Ensure compliance with regulatory and industry standards (FDA, MDD/MDR, ISO, ASTM, etc.) as appropriate.
- Technical team member for non-conformances, deviations, CAPAs, and root cause investigations
- Assist with preparation and/or review of documentation in accordance with relevant internal SOPs
- Perform preclinical needs assessments
- Support sustaining and process engineering efforts during process scale-up and manufacturing improvement initiatives
- Act as Subject Matter Expert.
- Maintain a safe work environment
- Other duties as reasonably assigned by VP, R&D

Requirements:

- Minimum bachelor's degree in Material Science, Bioengineering, Chemistry, or related technical discipline. Advanced degree highly preferred
- 5+ years of medical device and design control experience, 2+ years of supervisory experience preferred
- Project management experience, PMP certification is 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.
- Experience in tissue engineering and biomaterials
- Experience in developing medical devices with animal tissue components a plus
- Ability to travel as needed domestically and internationally.
- 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



Please apply online at <http://collagensolutions.com/company/careers> or via email at careers@collagensolutions.com

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