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**JOB DESCRIPTION**

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**POSITION** Manufacturing Engineer**SUPERVISOR'S TITLE:****POSITION OVERVIEW:** The Manufacturing Engineer will be responsible for supporting process development and operations in a GMP certified manufacturing facility for collagen-based medical products. They will support the manufacture of the base polymerizable collagen protein and associated collagen materials, ensuring production, performance, and quality standards are consistently met. Initial responsibilities will focus on finalizing process steps, documenting, and validating the manufacturing process for commercial production. This individual will interface with product development and quality and regulatory team members to ensure that company goals and objectives related to regulatory submissions and product launch are achieved.

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**QUALIFICATIONS:****Required:**

- BS in engineering or equivalent

**Preferred:**

- MS in engineering or equivalent
- Manufacturing process engineering experience in GMP environment
- Protein purification, biologics, and/or medical device manufacturing
- Familiarity with medical device quality management systems
- Familiarity with ISO 13485

**Skills & Competencies:**

- Process engineering
- Process design
- Equipment validation and qualification
- Project management skills
- Able to identify problems and develop potential solutions
- Strong communications skills
- Cross-functional team leadership
- Collaborative skills
- Attention to detail

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**RESPONSIBILITIES:****Duties/Responsibilities:**

- Develops and implements equipment qualification and validation protocols
  - Assist in transitioning lab scale manufacturing process to pilot scale in new facility
  - Facility startup activities
  - Developing equipment specifications, ordering and receiving equipment
  - Accountable for compliance with appropriate GMP and other regulations and standards
  - Develop and evaluate potential process improvements with a focus on efficiency and quality
  - Execute manufacturing protocols consistently and in accordance with cGMP
  - Identifies areas for improvement and works with appropriate team members to implement
  - Performs other related duties as assigned
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