

Product/Process Engineer, Collagen Processing

Company Overview:

MIACH Orthopaedics, Inc. is a privately held company located in Westborough, Massachusetts, dedicated to developing bio-engineered surgical implants for connective tissue repair. The company's initial focus is on the Bridge-Enhanced® ACL Repair (BEAR®) technology as a viable alternative to conventional ACL reconstruction for patients who have sustained an ACL injury. The BEAR technology was pioneered by Martha Murray, M.D., at the Boston Children's Hospital Department of Orthopaedic Surgery with initial research funding provided by the NFL Players Association, Boston Children's Hospital and the National Institutes of Health.

The BEAR implant is designed to help regenerate a patient's own ACL tissue. It does not require a second surgery to remove a healthy tendon from another part of the leg or using a deceased donor's tendon.

The physician simply inserts the BEAR implant between the torn ACL ends and injects a small amount of the patient's own blood in the implant during a minimally invasive arthroscopic procedure. The combination of the BEAR implant and the patient's blood enables the body to heal the torn ends of the ACL back together.

Clinical studies have demonstrated that the BEAR implant restores torn ACL quality and size similar to a patient's non-injured ACL. It is hoped that by providing more normal anatomy and function of the knee, a higher percentage of patients will be able to return to activities they enjoy.

Currently, the BEAR implant is an investigational device and is only available in FDA approved clinical trials.

Position Overview:

Reporting to the VP of Manufacturing, the Product/Process Engineer, Collagen Processing is responsible for transferring and establishing the process to produce the BEAR implant in the R&D lab, meeting all specifications. The Product/Process Engineer, Collagen Processing will support in establishing the R&D lab and independently manage the day to day activities within the lab, proactively identifies and develops new capabilities where required. She/he will develop and potentially verify/validate new test methods to fully characterize the BEAR implant and supports innovation for future products leveraging the BEAR technology

Duties/Responsibilities:

- Establish and improve BEAR implant manufacturing process in Miach R&D Lab
- Support regulatory filing objectives by
 - Conducting and documenting Design Verification and Validation testing
 - Supporting all Design Control activities
- Work hand in hand with contract manufacturer to implement identified process improvements, including
 - Yield and efficiency improvements
 - Product characterization and in-process methods and controls
- Drive further process & product development and support all innovation efforts
- Support IP activities regarding product and process
- Perform other activities, as needed

Education/Experience:

- BS or MS degree in biomedical engineering, biomaterials engineering, chemical engineering or related discipline
- Must have 5+ years of experience in processing animal derived tissues on an R&D or pilot scale. Process development experience is a plus
- Must have experience in managing an R&D lab
- Must have experience in developing and verifying/validating test methods, preferably mechanical and chemical in a Medical Device regulated environment
- Must have experience in medical devices, Class III preferred
- Must have experience in the testing, evaluation and optimization of tissue based medical devices
- Experience in orthopedics or sports surgery preferred
- Willing to travel to support clinical and corporate activities.

Skills/Competencies:

- Ability to 'roll-up' sleeves and do what it takes to get the job done
 - Practical, results oriented mindset with a strong bias towards action and experimentation
 - Strong technical acumen
 - Ability to effectively prioritize and manage multiple tasks at the same time
 - Excellent verbal and writing skills, specifically technical writing;
 - Ability to communicate at multiple levels of the organization and effective at presenting results and findings to technical and non-technical staff and partners
 - Strong interpersonal skills with ability to collaborate effectively across the organization and with the clinical partners
 - Must have strong attention to detail and be highly organized
 - Ability to travel up to 20%, possibly higher during onboarding (first 90 days)
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Miach Orthopaedics actively recruits individuals with an entrepreneurial spirit and drive for excellence. We offer comprehensive benefits and competitive compensation packages. Miach is an equal opportunity employer and is committed to providing equal employment opportunities to all qualified candidates and employees.

Interested candidates should submit a cover letter and resume to our Human Resources Department at hr@miachortho.com. Please include the job title of the position you are applying for in the subject line. Please note that agency phone calls or submissions will not be accepted at this time.


