

Location: Cleveland, OH

Reports to: Vice President, Engineering

Duties and Responsibilities: In this role, the individual is primarily responsible for performing activities in support of the development and manufacture of tissue and polymer based medical devices based on proven scientific concepts. Duties and responsibilities for this position include (but are not limited to):

- Interpret customer and market needs into documented product requirements
- Refine product and process characteristics through research and experimentation
- Evaluate product risks using traditional methods and implement control mechanisms to reduce risks to acceptable levels.
- Create product specifications, raw material specifications, and manufacturing procedures.
- Demonstrate the ability of products to meet requirements through verification and validation testing.
- Become familiar with and follow design control procedures according to FDA and ISO requirements.
- Plan and manage project work in accordance with defined deliverable targets.
- Support regulatory product submissions through testing and documentation.
- Specify materials and equipment required to achieve objectives.
- Identify and direct work with outside strategic partners as required.
- Research scientific and clinical publications to support methods or conclusions
- Generate technical reports, making data-based recommendations for the products.
- CAD design of product, tooling and fixtures as required
- Comply with regulatory guidelines for design control

Qualifications: The candidate will have the following qualifications:

- A Bachelor's degree in Engineering or a related field is required.
- Undergraduate experience with tissue engineering and/or polymer science is preferred, however any prior experience with medical devices is desirable.
- Experience working in cleanroom environments is highly desirable.
- Strong written and verbal communication skills, with the ability to work closely with both internal and external team members.

- Proficient in the use of personal computers, including the use of Microsoft Outlook, Microsoft Word and Microsoft Excel.
- The ability to make necessary decisions and/or take action required to carry out job duties.
- The ability to operate independently and to self-manage all activities in working towards the common goals of the organization.

Language Skills:

Candidate must have the ability to read, analyze and interpret general business periodicals, professional journals, technical procedures and government regulations written in the English language. Must also be able to effectively present information and respond to questions from groups of managers, clients, customers and the general public in the English language.

Work Environment:

The individual will split time between a typical office environment and the manufacturing area, which consists of a mix of cleanroom and lab-style manufacturing spaces. When in the cleanroom, the individual will be expected to wear designated gowning and follow standard anti-contamination practices. All areas are environmentally controlled.

Physical Requirements:

The individual will be expected to perform standard office work, which involves writing, typing, filing and other work performed at a desk or in a normal office environment.

Additionally, the individual will be expected to perform lab and manufacturing work, which involves taking measurements using hand-held and large computer-controlled tools, measuring and mixing chemicals, and operating large pieces of laboratory and manufacturing equipment.


Travel:

Minimal travel is expected.

Disabilities Discrimination:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed in this job description are representative of the knowledge, skill and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Job Description Approval:

Immediate Manager	<u>Robert Priest</u> <i>Print Name</i>	<u> 20-Apr-2017</u> <i>Sign/Date</i>
Next Level Manager	<u>n/a</u> <i>Print Name</i>	<u></u> <i>Sign/Date</i>
President and CEO	<u>Peter Gingras</u> <i>Print Name</i>	<u></u> <i>Sign/Date</i>