Interested Parties should contact:
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508 359 4120

## Position: Manufacturing Engineer (Med Device) Location: MA

Our client is a pioneering biotechnology company in the emerging field of regenerative medicine. Their goal is to regenerate and restore organ function of the esophagus, trachea or bronchus damaged by cancer, trauma, infection or congenital diseases.

The company's novel technology is engineered to stimulate the body's signaling pathways and natural healing process to regenerate and restore organ function. The technology is based on over 20 years of scientific progress in the fields of tissue engineering, cell biology and material science / combining the best attributes of a synthetic scaffold with tissue engineering and cell biology to create what may be a revolutionary method of addressing organ damage.

**Job Summary**
Develops, establishes and maintains Manufacturing Engineering methodologies, systems and practices which meet the applicable regulatory requirements, best industry practices and procedures. Serves as a Manufacturing representative to improve awareness of the cGMPs and other requirements to the manufacturing personnel. Instrumental in preparing the manufacturing facility for cGMP manufacturing based on established timelines. Communicates manufacturing initiatives in support of departmental, operational goals and priorities. Acts as the liaison between manufacturing and Quality ensuring that the cGMP requirements are implemented and followed.

**Responsibilities**

- Evaluates manufacturing processes by designing and conducting process improvement programs; applying knowledge of product design, fabrication, assembly, tooling, and materials; conferring with equipment vendors; soliciting observations from operators and providing guidance to operators as related to best cGMPs.
- Provides support to the Manufacturing Director/Manager. Works under minimal supervision.
- Develops manufacturing processes by studying product requirements; researching, designing, modifying, and testing manufacturing methods and equipment; conferring with equipment vendors.
- Generates manufacturing documentation (manufacturing specifications, procedures, etc).
- Conducts and documents applicable training to manufacturing personnel.
- Leads equipment IQ/OQ/PQ, Process Validation activities.
- Leads facility qualification activities.
- Develops and updates pFMEA documentation.
- Improves manufacturing efficiency by analyzing and planning work flow, space requirements, and equipment layout.
- Assures product and process quality by designing testing methods; testing finished- product and process capabilities; establishing standards; confirming manufacturing processes.
- Provides manufacturing decision-making information by calculating production, labor, and material costs; reviewing production schedules; estimating future requirements.
- Prepares product and process reports by collecting, analyzing, and summarizing information and trends.

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- Provides manufacturing engineering information by answering questions and requests to cross functional teams.
- Assures the development and execution of manufacturing systems which effectively identify and resolve manufacturing quality issues.
- Maintains product and company reputation by complying with US manufacturing regulations.
- Keeps equipment operational by coordinating maintenance and repair services; following manufacturer's instructions and established procedures; requesting special service.
- Maintains product and process data.
- Completes design and development projects by training and guiding manufacturing technicians.
- Contributes to team effort by accomplishing established Company and specific Manufacturing goals and objectives.

**Qualifications**

Bachelor Degree required.
5-8+ years of quality experience in the medical device industry; combination product experience is a plus.
Working knowledge of cGMP compliance/best industry practices for medical device products.
Ability to deal with complexity and changes in a fast pace environment.
Ability to present technical Information.
Understanding of compliance nuances related to Combination Products is a plus.
Strong knowledge of US Quality System Regulatory requirements (cGMPs-21 CFR part 820, at minimum. 21 CFR part 210-211, part 600, part 4 and ISO 14971-Risk Management, is a plus).
Strong knowledge of Risk Analysis and related tools.
Ability to effectively communicate with a broad spectrum of people having varying backgrounds, education, and experience.
Ability to act as a change agent and drive/influence change as well as effectively lead and motivate team members to achieve goals.
Demonstrated success in delivery of key milestones against tight timelines.
Aptitude to succeed in the culture of a fast-paced, publicly traded, start-up biotechnology company.
Strong written and verbal communication skills.
Strong technical writing skills.

**Additional Information**

This is a full-time position
The Manufacturing Engineer will report directly to the Director/Manager of Manufacturing.
Minimal travel may be required (10% or less).
Must be able to work in a team environment and with minimal supervision.