

Job Specification

Title: Process Development Engineer

Reports to: Principal Manufacturing Engineer

Date created: December 2023

About CardiacBooster:

CardiacBooster is a medical device company developing a new and innovative device to support the heart. Heart support devices are used by interventional cardiologists to stabilize patients in times of cardiogenic shock and acute heart failure. We are an enthusiastic team with diverse backgrounds and expertise, located in Galway, Ireland, and Nijmegen, Netherlands. CardiacBooster is an equal opportunity employer.

Job Description:

The PD Engineer will be an experienced engineer with good knowledge of medical device development for interventional cardiology. Key responsibilities include supporting the development and implementation of manufacturing and assembly processes associated with the company's pVAD catheter, design feedback & input, as well as working with the suppliers of catheter components. The PD Engineer will work closely with his/her counterparts responsible for device development and characterization, other development functions, and Quality. They will share the responsibility of realising CardiacBooster's full potential.

The successful candidate will have entrepreneurial spirit, the required persistence and resourcefulness to succeed in a start-up environment, and the ability to work in a self-directed manner. They will have hands-on knowledge and experience in both the development of cardiovascular devices and the processes required to manufacture them. They will be a team player and have excellent communication skills as well as good industry knowledge. They will work from the company's office in Ireland and be able to travel occasionally.

Key Responsibilities

- Develops manufacturing processes, materials, and methods as part of the CardiacBooster product development team, using in-house and external development paths
- Designs, specifies, procures and qualifies process fixtures and equipment
- Develops Work Instructions and other supporting documentation (e.g. calibration and maintenance) for manufacturing processes
- Executes process characterisation and validation activities
- Becomes a technical expert in the assembly and manufacture of our products, and provides technical guidance to other team members
- Builds Quality into all aspects of work by maintaining compliance to all quality requirements
- Works with internal cross-functional teams and contract manufacturers or design firms to ensure system design, architecture, and verification/validation meets design input
- Supports cleanroom setup, fit-out & validation

- Evaluates relevant process & manufacturing technologies and strategically identifies opportunities to implement them
- Executes project plans, tasks and deliverables. Manages time to meet project deadlines.
- Uses structured problem-solving techniques and statistical methods for data driven analysis and decisions

Skills, Qualifications & Experience

- Minimum of three years of medical device development experience, and have either a primary or Master's Degree in a relevant engineering discipline such as polymer, mechanical, manufacturing or biomedical engineering.
- Experience in fabrication and manufacture of catheter based medical devices; experience in large calibre delivery systems is an advantage.
- Product and process development, and new product introduction skills in medical devices are a must. In particular:
 - Fixture and equipment design & specification
 - Validation of processes and process equipment
 - Development of Work Instructions and Calibration & Maintenance activities for manufacturing processes
- Strong knowledge of materials and process capabilities used in catheter based medical devices
- Strong working knowledge and ability to use statistical techniques, Six Sigma and Minitab analysis to support manufacturing processes.
- Proficiency in Solid Works 3D modelling would be an advantage
- Experienced in ISO 13485 compliant manufacturing & Risk Management tools e.g. pFMEA
- Ability to work within a team; fully motivated to achieve and demonstrate best practices in line with company objectives.
- Excellent verbal communication skills to enhance collaboration and written skills to prepare/execute/communicate plans and reports
- Strategic Planner with successful scheduling & execution results

The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not intended to be construed as an exhaustive list of all responsibilities, duties, and skills required of personnel so classified.

Applications:

- Please submit your application, including resume, to hr@cardiacbooster.com