Job Specification

Title: **Test Engineer**

Reports to: **R&D Manager/Director**

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 acute heart failure (cardiogenic shock) or patients undergoing high-risk coronary procedures (high-risk PCI). Our objective is to overcome the limitations of current assist devices by providing interventional cardiologists with a more effective and less invasive device.

CardiacBooster was founded in 2018 as a Radboud UMC spin-off. We are an enthusiastic team with diverse backgrounds and expertise located in Nijmegen the Netherlands and in Galway Ireland. CardiacBooster is an equal opportunity employer.

Job Description:

The Test Engineer plays a key role in developing a safe and effective device. Working from the requirements, you will have a critical eye on the physical behavior of CardiacBooster's medical device. Your output will be used as design input. Together with the rest of the team, you will share the responsibility of realizing the full potential of CardiacBooster's technology. The successful candidate will have entrepreneurial spirit, the required persistence to succeed in a start-up environment, and the ability to work in a self-directed manner with minimal direction and supervision. You should have hands-on knowledge and experience in the development and maintenance of test platforms for validation and verification. The Test Engineer will work from the company's office in Galway and be able to travel occasionally.

Key Responsibilities

- Your key responsibility is to measure and quantify the physical characteristics of the device by experimental design. Your knowledge of solid and fluid mechanics, and other areas of physics should translate into hardware and software implementations of test platforms and their validation, including test protocols and data analysis tools.
- You will work closely with your counterparts responsible for designing and manufacturing the pVAD device.
- Understand the physical and physiological drivers and boundary conditions of pVAD design and translate them into concrete research proposals.
- Develop new test methods in partnership with device and scientific SMEs. Develop test capabilities, processes and protocols to support the development, verification, and validation of the company's catheter device.
- Document test method procedures and keep them updated in line with changes to standards.
- Develop, design, document and perform test method validations.
- Control the scheduling of testing for efficient throughput. Manage the stock level of test consumables and device accessories to prevent interruption to planned testing.
- Develop and maintain the company's bench testing, technologies & competencies. Manage the test equipment in the laboratory (e.g., PM's, CALs, software & hardware updates).
- Keep informed of new test standards, techniques or equipment and evaluate their impact on future or historical test data.
- Good communication with peers and management in the continuous feedback loop between device design and validation testing. Present updates and summaries of test data using statistical techniques where necessary.
- Perform demonstrations of device operation for visiting customers, new starters, executives or investors.

Skills, Qualifications & Experience

- The successful candidate will have a minimum of four years of medical device development experience, and have either a Master's or primary Degree in a relevant engineering/scientific discipline such as applied physics, mechanical engineering, biomedical engineering, or equivalent experience.
- Competent in applying statistical techniques to interrogate test data and draw conclusions. Experience developing and executing DOE. Experience developing and executing Gauge R&R studies.
- Experience with device reliability or fatigue testing techniques
- Competent technical writer.
- Experience with physical measurement equipment, sensors and simulated use testing.
- Programming skills in Matlab + Matlab Simulink.
- Experience in qualification of medical / cardiovascular devices, with structural heart experience an advantage. Basic knowledge of the V-model approach to verification & validation testing is preferred.
- Ability to source, evaluate and manage suppliers of equipment, calibration services and sub-contract testing.
- Experience with change control and ability to process changes efficiently.
- Must have the ability to organise and control test schedules.
- Good communication skills and ability to tailor those communications depending on the audience.
- Willingness to travel on occasion (e.g., to Nijmegen, Netherlands site).
- Experience working to regulatory requirements of 21CFR820, MDR and ISO13485.
- Experience using 3D CAD modelling software (SolidWorks preferred).
- Proficient in the use of office software packages (e.g., Microsoft Outlook, Word, Excel, PowerPoint etc.).
- Perform training of personnel (e.g., test methods, work instructions & procedures).
- Contribute to the development of resources and competencies of the test laboratory.

Applications:

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

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.