Job Opening

Title: Senior R&D Engineer – Control System

Reports to: VP of R&D

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 Senior R&D Engineer - Control System will be part of CardiacBooster's R&D team. The key responsibility of the Senior R&D Engineer - Control System is the design of an electromechanical driver control system ("Control System"), which actuates and controls the CardiacBooster pump head. This driver console must become an intuitive interface between the clinical user and the driving mechanism of the CardiacBooster's pVAD. The Senior R&D Engineer - Control System will work closely with his/her counterparts, in test and product development engineering as well as third party development partners. As a team, they are responsible for matching the pVAD system technical requirements and interface design. Furthermore, his/ her task is to give support in other mechatronic challenges that are encountered in in-house device development and testing of the pVAD devices.

He/She 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. The Senior R&D Engineer - Control System will have hands-on experience in the design of electromechanical machinery for the medical devices industry and can work from either the company's office in Galway or Nijmegen and be able to travel occasionally.

Essential Job Responsibilities:

- Translation of pump head functional requirements into control system output requirements and a detailed design specification.
- Ownership and oversight of the electro-mechanical design of control system (console, actuator & pump elements).
- Continuous calibration of the driver requirements with the stakeholders
- Ability to achieve the right balance between technical functionality and user-friendliness.
- Be the project leader from developing initial prototypes, through FIH standard systems and on to series manufacturing at CardiacBooster's vendor(s).
- Conduct & support risk management activities related to development i.e. PHA, DFMEA etc.

- Conduct or manage testing of devices and components for feasibility, verification & validation or root cause investigations.
- Integrate the learnings from user/Control System interactions to improve the usability of the device.
- Document development work in laboratory notebooks and technical reports. Summarise information and present key findings and conclusions.
- Improve the efficiency of cross-functional workstreams in the development of the device.
- Coordinate with colleagues and suppliers to ensure deliverables and milestones are achieved.
- Provide input to relevant QMS procedures in development, risk management, instructions for use; also to usability, pre-clinical, DV&V and clinical protocols.
- Draft invention disclosures and address queries from patent agents.

Required Qualifications & Characteristics:

- Responsibility to specify, source, test and qualify the appropriate electronic, gas and mechanical elements of the Control System (e.g. HMI consoles, sensors, linear actuators, pneumatics, PLCs, sensors, actuators).
- Minimum 5 years industrial experience in developing electromechanical systems and interfaces for medical devices.
- Educated to NFQ level 9 or above in a relevant engineering discipline (mechatronics, electrical or mechanical). NFQ level 7/8 with additional, relevant experience also considered.
- Knowledge of IEC 60601-1 and the basic safety and essential performance requirements of medical electrical equipment.
- Conduct or manage testing of software and hardware elements for feasibility, verification & validation or root cause investigations. Basic knowledge of the V-model is preferred.
- Ability to analyse and troubleshoot the machine elements of the Control System.
- Programming skills in real-time control environments. Experience with PLC design is essential.
- Experience with applying Human Factors Engineering principles in the development of interfaces for electromechanical medical devices.
- Working knowledge of data interrogation and applicable statistics.
- Ability to navigate uncertainties, queries, opinions and requests and maintain focus on higher priority work communicating at a level of detail appropriate to the intended audience.
- Ability to negotiate agreement on path forward, develop a work-breakdown, execute a plan and provide updates on progress.
- Working knowledge of ISO13485, ISO14971, MDR, and relevant FDA guidances.
- Experience with 3D CAD design (SolidWorks) is preferred.
- Excellent communication skills in English and preferably one other European language
- Knowledge of the patent process is an advantage.

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.