

Job Opening

Title: Senior R&D Engineer - Catheter System

Reports to: Manager/Director, 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 - Catheter System will be an experienced medical device engineer with intimate knowledge of medical device development for interventional cardiology. The key responsibility will be the development of the company's pVAD catheter, including the development of the design, the associated manufacturing and assembly processes, as well as the selection and management of suppliers of catheter components. The Senior R&D Engineer - Catheter System will work closely with his/her counterparts responsible for device characterization, other development functions, as well as quality affairs and marketing functions. He/She will share the responsibility of realizing the CardiacBooster's full potential.

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. He/She will have hands-on knowledge and experience in the development of cardiovascular devices. The Senior R&D Engineer - Catheter System will be a team player and have excellent communication skills as well as in-depth industry knowledge. The Senior R&D Engineer - Catheter System will work from the company's office in Galway and be able to travel occasionally.

Essential Job Responsibilities:

- Design the Catheter System from user and expert inputs applying materials science and engineering first principles. Produce working prototypes of the Catheter System appropriate to the particular phase of development.
- Develop assembly and manufacturing processes for the company's pVAD catheter.
- Anticipate risks and challenges; proactively ensure availability of adequate mitigation plans.
- Development of DFMEA and PFMEA or similar risk management tools.
- Manage relationships with third party development and manufacturing vendors.
- Coordinate with colleagues and suppliers to ensure deliverables and milestones are achieved.
- Conduct or manage testing of devices and components for feasibility, verification & validation or root cause investigations. Basic knowledge of the V-model is preferred.
- 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.

- Provide input to and maintain compliance with Quality procedures.
- Draft invention disclosures and address queries from patent agents.

Required Qualifications & Characteristics:

- Responsibility to specify, source, test and qualify the geometry and materials of the Catheter System.
- Self-directed engineer with entrepreneurial drive with detailed understanding of interventional cardiology device requirements, preferably structural heart applications.
- Minimum 5 years industrial experience in developing reinforced catheter and balloon systems for medical devices.
- Educated to NFQ level 9 or above in a relevant engineering discipline (Polymers, Mechanical, Materials Science or Biomedical). NFQ level 7/8 with additional, relevant experience also considered.
- Expert in materials selection and processing methods for thin plastic film components and membranes, balloons, single and multilumen tubing, reinforced braided/plastic composite tubes.
- Experience with materials selection and processing methods for solvent and adhesive bonds, insert and overmoulding techniques.
- Have an established vendor network relevant to the device type.
- Experience with developing tests necessary to measure the performance of Catheter Systems in development, especially for novel devices where established techniques or international standards may not yet exist.
- Working knowledge of data interrogation, DOE and applicable statistics.
- Ability to navigate uncertainties, queries, opinions and requests and maintain focus on higher priority work.
- 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 using 3D CAD software is an advantage (SolidWorks 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.