Job Opening

Title: Manager, Quality Affairs

Reports to: CEO

About CardiacBooster:

CardiacBooster is a young 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. We are an enthusiastic team with diverse backgrounds and expertise, and are located on the NovioTech Campus in Nijmegen, Netherlands. CardiacBooster is an equal opportunity employer.

Job Description:

The Manager, Quality Affairs, will be an experienced medical device professional with intimate knowledge of class III devices in interventional cardiology. The key responsibility of the Manager, Quality Affairs, will be to lead and oversee the development of the company's pVAD catheter, and to lead the catheter development team. The Manager, Quality Affairs, will work closely with his/her counterparts responsible for device development as well as with other functions. He/She will provide team and project leadership, and share the responsibility of realizing the CardiacBooster's full potential.

The successful candidate will be thorough, analytical and have experience in setting up a quality management system for class III medical devices. He/She will have 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 and maintenance of a quality system for cardiovascular devices. The Manager of Quality Affairs will have excellent communication and coordination skills. The successful candidate will look back on a minimum of four years of Quality Affairs experience, and have a Master's Degree in a relevant engineering discipline such as biomedical engineering, or equivalent experience. The Manager, Quality Affairs, will be able to travel a part of his/her time.

Essential Job Responsibilities:

- Develop, implement and manage robust quality management system; ensure compliance with quality system
- Lead establishment of risk management and risk control processes
- Coordinate comprehensive risk analysis
- Support product development and regulatory functions
- Anticipate risks and challenges; proactively work with relevant functions to ensure development of adequate mitigation plans
- Ensure proper qualification of development and manufacturing vendors

Required Qualifications & Characteristics:

- Intimate understanding of the medical device industry and interventional cardiology device requirements
- Experience in establishing a QMS within a medical device start-up
- Experience with class III cardiovascular devices
- Excellent communication skills in English and preferably one other European language
- Master's Degree in a relevant engineering discipline, or equivalent experience

Applications:

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