SENIOR MECHANICAL ENGINEER

The senior mechanical engineer will lead the BiVACOR Inc. Mechanical Engineering team to design, develop and test all mechanical engineering aspects of the BiVACOR implantable artificial heart. With a clear technical vision, the senior mechanical engineer is required to facilitate and manage the design, manufacturing, verification and validation of the mechanical components of the BiVACOR implantable artificial heart.

The high-level responsibility of this position will require broad knowledge of and clear decision making in different aspects of engineering: statics, dynamics, vibration analysis, fluid and thermo-dynamics, material selection, and process manufacturing. This roll requires the authoritative management of both the in-house development effort and external consultant assignments, while transforming the project from a prototyping stage to a professional certified environment.

BiVACOR is looking for a motivated team member who is keen to contribute to this early stage and dynamic project. This role requires creativity and strong leadership and organizational talent. Being able to find optimized solutions in a multidisciplinary and dynamic development will be key to the success of the project.

RESPONSIBILITIES

- Planning and execution of development paths towards clinical trials and commercial device release.
    - Device design
    - Define manufacturing processes & manage vendors
    - Plan and perform V&V
    - Risk analysis
- Technical leadership for achieving design freeze of all ME subsystems including:
    - Pump design including cutting edge manufacturing techniques and material selection;
    - Hydraulic and electrical connectors (including hermeticity);
    - Patient interfaces (cables & controllers; excl. electronics).
- Utilize recognized engineering theory to analyse technical problems and find solutions.
    - Management of the internal engineering team and external consultants and vendors.
- Define and control required documentation.
    - Technical drawings, specifications, SOPs, work package instructions
    - Incoming inspection procedures
    - Design verification and test reporting
- Assist in the preparation of required documents for regulatory submission.
    - FMEA / CAPA
    - Ensure compliance of al ME systems to the relevant standards and regulatory practices.
- Collaborate with other internal departments and QM to optimize group interaction, facilitate system level solutions and achieve milestones with strict deadlines.

REQUIREMENTS

- Bachelor’s Degree in Mechanical or equivalent
- Highly familiar with ISO 13485 & medical QM systems
- Familiarisation with ASME Y14.100, ASME Y14.5M-2009, ANSI/AAMI/ISO 14708-5:2010 preferred
- Broad knowledge of hands-on experience with design, optimization, and manufacturing techniques
- Minimum of 5 years in medical device development field
- Minimum of 5 years project management experience with a track record of finished products

Submit Resume and cover letter to admin@bivacor.com