MANUFACTURING ENGINEER (MFE)

The Manufacturing Engineer will contribute to the development of the design for manufacturing (DFM) process of the BiVACOR rotary total artificial heart device.

This position will undertake and document experiments that optimize the device design and process in order to reliably and repeatedly produce a device which meets the design input specification. This position will work closely with management, internal company engineers, and external vendors to improve tooling and component quality, whilst also investigating cost reduction and quality initiatives to assure the long term value and viability of products.

This position requires a hands-on candidate with superior communication and organizational skills as well as problem solving and technical skills. The candidate must be comfortable with complexity and ambiguity, whilst keeping the bigger picture in mind.

RESPONSIBILITIES

- Conduct an extensive design for manufacturing review of current manufacturing processes in cooperation with key vendors.
- Develop and validate manufacturing processes from prototype to product.
    - Equipment identification, design, installation and validation.
    - Manage internal and external resources with a view to reduce cost and improve supply chain efficiency.
- Plan, schedule, conduct and coordinate detailed phases of engineering work relating to manufacturing.
    - Technically supervise or liaise with/coordinate the work of technicians.
    - Maintain 2D-3D CAD drawings.
    - Implement GD&T tolerance analysis as well as practices from ASME Y14.5 and ASME Y14.100.
    - Create Work Instruction documentation which describes manufacturing of the device.
- Process validation and design transfer to manufacturing.
    - Develop test plans to identify and define the acceptable tolerance range that meet deign input specifications.
    - Participate in failure analysis / corrective action activities in order to determine and direct design modifications.
    - Identify and manage process risk analysis and supplier management from prototype to product.
    - Provide input and support to regulatory affairs for regulatory submission.

REQUIREMENTS

- B.S. in Mechanical, Electrical, Biomedical or Manufacturing Engineering, M.S. desirable
- 5-8 years engineering experience including skills in product and process development, preferably in the medical device industry. A strong working knowledge of process characterisation, pFMEAs, MVP, IQ / OQ / PQ / PPQ, TMVs is desirable.
- An understanding of medical device quality regulations, practices and quality standards, such as ISO 13485, ISO 9001 and FDA quality system regulations.
- Competent computer software skills with word processing, database management and spreadsheets. Familiarity with industry best practices and applicable standards.

Submit Resume and cover letter to admin@bivacor.com