SNR. MANUFACTURING ENGINEER (SME)

The Snr. Manufacturing Engineer (SME) will contribute to the development of the design for manufacturing and assembly process of the BiVACOR rotary total artificial heart, while incorporating value engineering techniques. 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 aids in optimizing the device design and process to reliably and repeatedly produce the implantable components of the device, which conforms to the design input specification and meets the product requirement specifications.

For our location in Cerritos, CA we are looking for a hands-on candidate with superior communication and organizational skills as well as problem solving and technical skills and a willingness to travel nationally and internationally. 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.
  - Define product output specifications
- Plan, schedule, conduct and coordinate detailed phases of engineering work relating to manufacturing.
  - Technically supervise or liaise with/coordinate the work of technicians.
  - Review and Maintain 2D-3D CAD drawings.
  - Implement GD&T analysis as well as practices from ASME Y14.5 and ASME Y14.100.
  - Create work instruction documentation which describes manufacturing and assembly of the device.
- Manage the design transfer to manufacturing and develop then verify internal/external manufacturing process.
  - Scheduling, ordering, managing vendor relations, managing internal and manufacturing environment.
  - Verify the product and processes including statistical process control, material traceability.
  - Develop test plans to identify and define the acceptable tolerance range that meet design input specifications and product output requirement specifications.
  - Participate in failure analysis / corrective action activities 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

- BS in Mechanical, Electrical, Biomedical or Manufacturing Engineering, MS desirable
- 8-10+ 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 and FDA quality system regulations (design controls).
- Logistics and supply-chain experience is desired.
- Familiarity with industry best practices and applicable standards.

Submit resume and cover letter to admin@bivacor.com