EMPLOYEE POSITION DESCRIPTION

Job Title: Principal Manufacturing/Process Engineer	Department: R&D and Operations
☒ Exempt	☐ Nonexempt

Position Description:

The Principal Manufacturing/Process Engineer (PMPE) will report directly to the VP of R&D and Operations. S/he will lead all aspects of the supply chain and manufacturing of complex disposable and capital medical devices for the organization. The PMPE will work with the R&D, Quality, Systems and Regulatory teams to identify appropriate Contract Manufacturers (CMs) and manage relationships through the product lifecycle. Additionally, this position requires problem-solving skills experience and technical expertise (Six Sigma, DMAIC, etc.) and the ability to manage complex electromechanical projects and lead cross-functional teams to a successful and timely conclusion.

Principal Responsibilities:

The Principal Manufacturing/Process Engineer is a key position in the R&D and Operations organization. Major responsibilities include:

- Participates as a core team member for product development projects to ensure that manufacturability and cost are considered throughout the process.
- Identifies contract manufacturers for sub- and final assemblies of complex electromechanical medical devices. Negotiates contracts to establish fair pricing and priority commitments.
- Manages the supply chain to ensure that components for builds and inventory for commercialization are available according to sales forecasts.
- Identifies and collaborates directly with packaging contractors to design, build and test sterile medical device packaging to meet or exceed international standards.
- Drives operations and process risk management documentation including but not limited to user FMEA, process FMEA, and design FMEA.
- Utilizes Design of Experiments (DOE) to refine and improve designs and processes by identifying and optimizing the few vital factors from the many trivial factors.
- Analyzes various assembly strategies and design concepts using Design for Manufacturing and Assembly (DFMA) principles to reduce complexity, component count, and overall cost.
- Uses six sigma methods (DMAIC) and lean manufacturing principles to reduce variation and eliminate waste in the product and associated processes.
- Responsible for establishing and maintaining robust, stable, and capable manufacturing processes and validation processes that meet or exceed quality and operational expectations.
- Stays abreast of new technologies, processes, and tools associated with the medical device sector.
- Recommends the implementation of new technologies, processes, and equipment wherever logistically and financially justified.
- Helps to recruit, coach, and develop organizational talent.
- Functions well in a team environment.

The above statements are intended to describe the general nature and level of work being performed. They are not intended to be construed as an exhaustive list of all job responsibilities and duties.

Qualifications, Education & Experience:

- BS in electrical, mechanical, manufacturing, industrial or process engineering or related field.
- A minimum of 7 years of relevant experience, or an advanced degree with a minimum of 5 years of experience.
- Manufacturing/Operations experience in the medical device industry.

Must Have:

- Outstanding integrity, character, and trustworthiness; demonstrated evidence of leadership, creativity, adaptability, determination, and perseverance.
- Experience documenting medical device development according to Medical Device Regulation ISO 13485.
- Experience in medical product manufacturing/assembly operations.
- Very good written and verbal communication skills.
- Hands-on development of manufacturing and design processes.
- Experience designing and developing new products, processes, fixtures and equipment with SOLIDWORKS or other CAD software package.

Nice to Have:

- Experience working with contract manufacturers to produce consumable and capital medical devices.
- Excellent written and verbal communication skills.
- Electromechanical design experience.
- Green Belt Certification (Internal or ASQ).
- BB/Master Black Belt certification.
- Certified Manufacturing Engineer (CMfgE)

Working Conditions:

- Occasionally exerting up to 20 lbs. of force and lifting to 50 lbs.
- Significant work pace and pressure due to deadlines of a start-up organization.
- Office and lab environment where the engineer would stand or sit for most of the day at a desk or lab bench.
- Operate a computer, and other office equipment.
- Travel may be required (up to 10%).

Competitive salary and benefits package.

To Apply: Submit your resume to info@francismedical.com

Company Overview:

Francis Medical is committed to developing urological cancer treatments that are tough on cancer and gentle on patients, with a compassionate belief that minimally invasive therapies can effectively treat cancerous tissue. The company's foundation is a tribute to and legacy of the inventor's father, Francis Hoey, who endured prostate cancer treatments that had harsh implications on his everyday life before he died from the disease in 1991. Unfortunately, current prostate cancer treatments, which come with side effects like urinary incontinence and erectile dysfunction, are not much different than what Francis Hoey encountered. In contrast, water vapor technology applies the thermal energy stored in sterile water vapor to cancerous tissue via a simple transurethral procedure, potentially minimizing life-altering side effects.

Headquartered in Maple Grove, MN, Francis Medical is a spin-off of NxThera, a BPH company purchased by Boston Scientific in 2018. Francis Medical has closed on a $25-million round of Series A funding led mainly by previous NxThera investors. The company currently employs 24 people. The work environment is casual, high-energy, and collaborative, with the shared vision of making a difference in the lives of millions of men. More information on Francis Medical can be found at www.francismedical.com.