EMPLOYEE POSITION DESCRIPTION

Job Title: Manufacturing Engineer II	**Department:** Mfg Operations / Supply Chain
☒ **Exempt**	☐ **Nonexempt**

Company Description:

Francis Medical is a clinical-stage medical device company located in Maple Grove, MN that is developing urological cancer treatments that are tough on cancer and gentle on patients using water vapor technology. Francis Medical is currently executing a pivotal US-based clinical study of its Vanquish system and is beginning to work on the development of a next-generation version of the system. The Vanquish system is designed to deliver targeted and controlled water vapor to ablate / treat cancerous prostate tissue with the thermal energy stored in sterile water vapor.

Position Description:

The Manufacturing Engineering II role is responsible for providing mfg operations representation and support throughout the product lifecycle and project phases in accordance with SOP's, regulations, and standards. Responsibilities include providing technical oversight to ensure operational requirements are met, aligning internal and external resources, providing manufacturing line support, implementing lean mfg activities, and managing continuous improvement plans to optimize / focus on product quality, delivery, and cost of our existing manufacturing processes. This role will report directly to the Mfg Operations and Supply Chain Manager and work on projects with cross-functional impact.

Primary Responsibilities:

- Participate as a core team member in product development projects to ensure that manufacturability, scalability, mistake proofing (design of processes, equipment) and product cost (COGS) are considered throughout the process.
- Contribute to project plans by evaluating and providing input to the product development team. Initiate, plan, and drive strategic initiatives to accomplish operational goals throughout all product development phases.
- Identify, measure, analyze, and monitor KPI's throughout the manufacturing process. Troubleshoot / solve manufacturing issues and bottlenecks as they arise to improve product quality and delivery (in-process defects and non-conforming materials). Document issues and recommend practical and timely solutions. Identify process and yield improvement opportunities and provide technical solutions.
- Work on the development, improvement, and optimization of our manufacturing processes and systems (i.e., cost reduction, material and product quality, lean mfg). Improve the overall efficiency of the manufacturing operation while optimizing human work factors (ergonomics), product quality, and material flow.
- Implement lean manufacturing initiatives (process flowcharts, value stream mapping, single piece flow, line balancing, 5S, SIPOC) on internal and external manufacturing processes.
- Assess manufacturing capacity capabilities to meet production demand.
- Use six sigma methods (DMAIC) and lean manufacturing principles to reduce variation and eliminate process waste.
- Review, initiate, and approve change requests associated with process improvements including design verification, design and process validation, equipment qualifications, work instructions, trace forms,

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test data sheets, component release / changes, assembly drawings, specifications, packaging, and labeling. Propose change assessments and change implementation plans at suppliers.

- Ensure components are designed for reliability, manufacturability, availability, and cost; define component qualification strategies, develop qualification plans, and demonstrate component or assembly release readiness. Implement safeguards to maintain design integrity from unintended material and process changes to critical materials and processes through MSA agreements and demonstrated practices at the suppliers.
- Support NCMR and CAPA root cause analysis, action planning, implementation of supplier process improvements, determination of effectiveness, and evaluation of unintended consequences of changes.
- Identify, select, and onboard contract manufacturers for our sub-assemblies and finished good assemblies. Develop excellent supplier relationships through frequent site visits to observe the manufacturing environment and verify adherence to process and quality controls.
- Support implementation of standard work for critical supplier processes. Implement standardized part handling and shipping, component packaging, and product cleanliness.
- Improve supplier capabilities through process performance, component, and equipment development work. Establish, analyze, and evaluate supplier process stability and capability, develop statistical process control methods to signal manufacturing issues / meet quality and operational expectations.
- Execute tools such as PFMEA, root cause analysis, control plans, process development, and process validation.
- Utilize Design of Experiments (DOE) to refine and improve designs and processes by identifying and optimizing critical factors.
- Analyze various assembly strategies and design concepts using Design of Manufacture and Assembly (DFMA) principles to reduce complexity, component count, and overall cost.
- Create plans and reports that demonstrate technical rationale for associated decisions(s) (e.g. qualifications, risk assessments).
- Create and update product work instructions (assembly, test, labeling, packaging) and train operation personnel.
- Coordinate efforts to plan, procure, install and qualify tooling, fixtures and equipment.
- Develop new approaches, methods, and strategies for the company to evolve. Identify and explore opportunities for new and innovative technologies, processes, and equipment.

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.

Competencies / Skills

- Anticipates potential obstacles and develops contingency plans to overcome them.
- Refrains from "jumping to conclusions" based on minimal evidence; understands the value of collecting data and facts to drive decision-making.
- Looks for long-term strategic solutions rather than quick fixes to problems.
- Explores different ideas; views situations from multiple perspectives; brainstorms multiple solutions.
- Proposes alternative ways to view or define problems; is not constrained by conventional thinking

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- Able to work and collaborate cross-functionally, build relationships, and contribute as an effective team player (functions well in a team environment).
- Is self-directed, "hands-on", problem solver with the ability to handle multiple tasks and projects simultaneously while maintaining high quality and timeliness of deliverables. Able to independently provide technical solutions to a wide range of difficult problems with imaginative, creative, thorough, and practical solutions that are consistent with organizational objectives.
- Effective verbal and written communication, analytical, and interpersonal skills.
- Able to effectively communicate engineering information / 'language' to production team personnel.

Required Qualifications, Education, & Experience:

- Bachelor of Science degree in manufacturing, industrial, or mechanical engineering from an accredited college or university
- Minimum of 3 years of manufacturing engineering experience, preferably within the medical device or a highly regulated industry
- Experience in applying lean manufacturing concepts and methodologies such as continuous improvement, elimination of waste, 5S, kaizen, kanban, value stream mapping, and visual management
- Demonstrated understanding, knowledge, and experience in mfg engineering principles - Design for Manufacturing (DFM), PFMEA, DOE's, and process validations

Preferred Experience / Certifications

- Experience in the application of statistical methods, tools, and analysis software (JMP / Minitab)
- Experience in structured problem solving and root cause analysis
- Lean facilitator or practitioner certification
- Lean Six Sigma Green Belt
- Experience working in a fast-paced environment (small company / start-up)
- Experience with high-volume, single use disposable manufacturing
- Knowledge of cleanroom principles and standards. Understanding of contamination control procedures.

Working Conditions

- Light work, exerting up to 20 lbs. of force or less
- Significant work pace and pressure due to deadlines
- Stand or sit for 8 hours per day
- Travel to suppliers as needed

Competitive salary and benefits package.
Local candidates only.
To apply: Submit your resume to hr@francismedical.com