Job Description

Job Title: Principal Engineer, New Product Introduction	**Department:** Operations
Reports To: Director, New Product Introduction	**Revision Date:** Nov. 11, 2016
FLSA Status: Exempt	

POSITION OVERVIEW:

The Principal Engineer, New Product Introduction (NPI) will report into the Director of NPI. He / she should have a strong product development background with exposure to design and manufacturing of capital equipment in the medical device field. He / she will lead cross functional teams through performance improvement, new feature set, design for manufacturability & serviceability, and cost reduction programs on a next generation dialysis system. He / she will also contribute as an individual team member. He / she will provide hands-on technical leadership and resource management to execute multi-disciplinary projects. The Principal Engineer, NPI will proactively interact with and/or manage internal and external customers, suppliers, and contract manufactures.

MAJOR DUTIES AND RESPONSIBILITIES:

- Actively seeks out and takes ownership of design, process and supplier issues, and product improvement opportunities. Works cross-functionally to evaluate the priority of issues/opportunities and develops project plans accordingly.
- Provides hands-on technical and product development (e.g. quality system, design control, etc.) leadership to team members.
- Defines project objectives and ensures they are consistent with strategic and operational objectives of the business.
- Ensures product introduction project schedules are met, deliverables executed within the budgetary constraints of the business, and the organization is well-informed of project progress (i.e. at project update meetings, through technical and/or design reviews, etc.).
- Is able to manage personnel that are not direct reports but are involved in the project (e.g. Manufacturing, Quality, Regulatory, Supply Chain, and other R&D personnel).
- Finds creative ways to shorten project timelines and/or define interim steps that provide incremental value to the patient and/or business.
- Actively and independently leverages cross-functional relationships to ensure project objectives are met and product performance meets customer and quality requirements.

- Provide technical support for failure analysis and root cause investigation of product failures.
- Maintains a basic understanding of aspects of the product design outside of his / her direct responsibility. Is capable of contributing and/or managing a project team in these areas.
- Leads the development of product specifications and process specifications.
- Leads the development and execution of verification and validation test plans based on design specifications and applicable guidelines (e.g. industry and government guidelines and/or standards).
- Actively stays well-informed of new trends in dialysis treatment and competitive products.

REQUIREMENTS/QUALIFICATIONS:

Required:

- B.S. in Mechanical or Electrical Engineering (or similar).
- Minimum of 8 years' experience in the mechanical design of medical products.
- Minimum of 5 years of experience with capital equipment
- Demonstrated success leading large cross-functional product development projects through Design Control.
- Strong track record of hands-on design development and testing.
- Experience managing multiple suppliers simultaneously.
- Experience with FDA regulations, GMP, and ISO requirements.
- Demonstrated ability to find creative ways to meet tight timelines.
- Strong communication and presentation skills.
- Very positively influential.
- Excel as both a team leader and individual contributor.

Preferred:

- M.S. or Ph.D in Mechanical or Electrical Engineering (or similar).
- Experience with medical capital equipment, fluidics design, sheet metal, and molded plastics design.
- Design for manufacturability and cost optimization experience.
- SolidWorks experience.
- MRP/ ERP familiarity.
- HALT/HASS experience.