

## **Staff/Principal Manufacturing Engineer**

Endologix, Inc. is a developer and manufacturer of minimally invasive treatments for aortic disorders. The company is located in Irvine, CA, has over 300 employees and is listed on NASDAQ (ELGX). Since launching in the U.S. in 2005, Endologix has experienced average annual growth of 60%+ and was the top performing med tech stock in 2009. The Company's Powerlink® System is an endovascular stent graft for the treatment of abdominal aortic aneurysms (AAA). AAA is a weakening of the wall of the aorta, the largest artery in the body, resulting in a balloon-like enlargement. More than 2 million people in the U.S. have AAA, with 200,000 new cases diagnosed every year. If left untreated, AAAs become increasingly susceptible to rupture. The overall patient mortality rate for ruptured AAA is approximately 75%, making it the 13th leading cause of death in the U.S. More information is available on the Company's website at [www.endologix.com](http://www.endologix.com).

Lead engineer responsible for the design and development of manufacturing processes, tooling, and fixtures in support of a next generation AAA device. Collaborates with the R&D organization to help facilitate the successful execution of the New Product Development Process and launching of robust products.

### ***Essential Duties and Responsibilities:***

- Design and develop manufacturing processes for new AAA products.
- Design and develop fixtures and tooling for new AAA products/processes.
- Work with R&D staff to ensure that design for manufacturability principles are applied to new processes.
- Plan, schedule, and complete projects in a manner consistent with business objectives.
- Develop and execute process validation protocols (IQ/OQ/PQ).
- Analyze process data and make decisions/recommendations relating to process capability and DFM.
- Support prototype and pilot production of new products, product changes, and enhancements in coordination with the Manufacturing and Quality Control functions.
- Investigate benefits and features of capital equipment and generate capital appropriation justifications.
- Create and maintain accurate documentation of concepts, designs concepts, tool drawings and shop orders in coordination with the Quality Assurance and R&D functions.
- Contact and address component and/or raw material issues with suppliers.
- Contribute to the intellectual property position of the company via invention and patent applications.
- Maintain current knowledge of medical, technical, and biomedical developments as related to company products.
- Maintain GMP compliance relating to Document Control, R&D, and Quality Assurance.
- Support company goals and objectives, policies and procedures, and FDA regulations.
- Ensure that all regulatory and internal policies are followed.
- Assist engineering manager in development of engineers providing assistance with coaching and mentoring.
- Identifies hazards and mitigates risk associated with identified hazards in Process FMEA.

### ***Education, Training, Skills and Experience Requirements:***

- Requires a Bachelor of Science degree in Engineering or related technical degree (i.e. physics or mathematics)

- Requires a minimum of 8-12 years related experience.
- Experience with catheters and interventional delivery systems is required.
- Knowledge in the following areas of manufacturing highly recommended, Balloon catheters, stent forming, PTFE, aseptic processing, pressure monitoring devices and injection mold design.
- Works on complex problems in which analysis of situations or data requires an in-depth evaluation of various factors.
- Exercises judgment within broadly defined practices and policies in selecting methods, techniques, and evaluation criteria for obtaining results.
- Has the ability to use statistic techniques when analyzing data and make rational and logical decision based on that analysis
- Applicable knowledge of Minitab, JMP, or other statistic tools
- Applicable knowledge of Solidworks or other CAD software (not a requirement but a desirable skill)
- Ability to handle multiple tasks simultaneously and ability to manage project timelines.

This is a multi-level position. The title of Staff or Principal will be based on the candidate's experience.