

## **Sr. Regulatory Affairs Specialist**

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).

The Senior Regulatory Affairs Specialist is responsible for the preparation and maintenance of domestic and international regulatory filings to meet corporate objectives, and for the timely completion of other assigned activities related to regulatory support activities worldwide.

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

- Prepare high quality international and domestic filings/registrations to established timelines
- Represent RA department in assigned project meetings and provide regulatory guidance as appropriate
- Coordinate with international contacts on product changes and regulatory notification/approval requirements
- Prepare reports to meet international regulations and reporting requirements.
- Review and approve test protocols and reports
- Work with Quality and Engineering in generating risk analysis, FMEA, and FTA reports
- Review and approve document change orders and prepare letters-to-file
- Update departmental procedures as required
- Ensure applicable domestic and international regulations related to Risk Management and Medical Device Reporting are met.
- Maintain up-to-date knowledge on international and domestic regulatory requirements
- Other duties as assigned by supervisor

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

- Minimum of 5-8 years experience in Regulatory Affairs. Experience with US Class III cardiovascular devices strongly preferred.
- Minimum bachelor's degree in a scientific discipline or equivalent.
- Extensive knowledge of global medical device regulations
- Comprehensive knowledge of quality systems and relationship to business
- Ability to facilitate and provide leadership when interpreting regulatory standards and guidances
- Ability to work in a fast-paced, technically challenging environment where drive is critical to success
- Must be self-motivated and self-disciplined and able to prioritize and handle multiple tasks and responsibilities
- Effective interpersonal skills/diplomacy and problem solving techniques
- Excellent applied thinking and technical writing skills
- Strong communication and organization skills required