

## **Director, Regulatory Affairs**

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 Director, Regulatory Affairs oversees all US and international regulatory affairs activities including regulatory compliance and submissions areas. Designs, plans and executes strategies for timely and high quality regulatory submissions in close collaboration with marketing, research and development, manufacturing, and clinical affairs partners for optimum achievement of corporate objectives. Provides overall management direction to the regulatory affairs team. Provides regulatory advice to other departments and executive management. Provides expertise in the interpretation of regulations into practical and workable plans. Interacts with regulatory agencies. Ensure that the manufacturing facility maintains all required U.S. and International certifications. Provides overall management of the company's document control and auditing systems.

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

- Manages and develops Endologix regulatory affairs personnel.
- Reviews and interprets existing or new external standards and regulatory requirements as they related to Endologix products and processes and provides timely, balanced regulatory strategic direction and advice to project teams and Executive Management to assure that regulatory and clinical requirements are incorporated into development processes.
- Effectively manages and maintains the Endologix Device Tracking System.
- Effectively manages and prepares regulatory documents and submissions to ensure timely approvals of products and processes in accordance with marketing strategies.
- Maintains international registrations and ensures compliance with post-approval commitments
- Ensures corporate compliance for licenses, government reporting requirements, etc.
- Assist in communication or presentations to government reviewers and/or inspectors as needed.
- Participate actively in budgeting process and maintenance.
- Other duties deemed necessary by Executive Management.

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

- BA/BS in Life Sciences or other technical discipline
- Minimum 8-12 years related experience in managing medical device regulatory affairs functions, preferably for Class III devices.
- Direct experience in writing investigational and marketing medical device applications for submission to US, European, and international regulatory authorities.
- Excellent written/verbal communication, leadership, management, negotiation, and team building skills.