

**Sr. Regulatory Affairs Specialist
(Requisition #8500-03)**

POSITION SUMMARY: The position is responsible for diverse regulatory functions, including but not exclusive to the development of Medical Device submissions and the implementation of Regulatory Compliance.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Prepare submissions for US and OUS regulatory agencies to gain approval to conduct clinical trials and to gain approval to market company's products.
- Perform country-specific product registrations and license renewals
- Maintain regulatory files (i.e., product catalog, submissions, vigilance and MDR reports, and correspondence)
- Maintain current knowledge of the developments and changes to applicable laws, regulations and industry standards
- Provide support function for federal (US) and notified body inspections of company's operations.
- Prepare and update product labeling that meets regulatory requirements.
- Perform labeling verification activities including preparation of specifications, protocols and reports
- Interact and interface with regulatory agencies as necessary.
- Provide support in maintaining customer complaint handling system
- Prepare and update departmental / standard operating procedures
- Provide assistance in product notification and recall activities.
- Work with cross functional teams to ensure proper coordination of information to meet regulatory requirements.

EDUCATION/CERTIFICATION: BS degree required, preferably in Engineering, Physical or Biological sciences. Regulatory Affairs Certification (RAC) or equivalent required

EXPERIENCE REQUIRED: Minimum 3 years of experience in US regulatory affairs, preferably with Class III devices, or equivalent combination of education and experience.

REQUIRED KNOWLEDGE:

- Knowledge of US / OUS medical device regulations, such as FDA QSR, FDA IDE/HDE/PMA regulations, and the European Active Implantable Medical Device Directive.
- Understanding of FDA compliance and GCPs.

SKILLS/ABILITIES:

- Excellent people skills, team oriented.
- Effective written and verbal communication skills
- Detail-oriented with strong organizational skills
- Strong computer skills (word processing and database programs)