Regulatory Affairs Specialist I

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:

- Assists with the preparation of submissions for US and OUS regulatory agencies to request approval to conduct clinical trials and to request approval to market the company's products.
- Maintenance of regulatory files including product catalog, complaint files, adverse event reports, regulations, correspondence, and submissions
- Provide support function for state, federal and notified body inspections of company's operations.
- Prepares and updates product labeling that meets regulatory requirements.
- Prepares labeling specification documents as well as labeling verification protocols and reports
- Interacts and interfaces with regulatory agencies as necessary.
- Provides support in maintaining the customer complaint handling system
- Prepares departmental operating procedures.
- Provides assistance in product notification and recall activities.
- Works with cross functional teams to help meet the teams' regulatory needs.

EDUCATION/CERTIFICATION: BS degree required, preferably in Engineering, Physical or Biological sciences.

EXPERIENCE REQUIRED: 1-2 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 EU Medical Devices Regulation.
- 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)