

The QiG group of Greatbatch Inc. is looking for a **Senior Regulatory Affairs Specialist** who can provide a high level of experience in regulatory requirements, strategy, timelines, and direction. This position will mentor product development teams while guiding them through the regulatory requirements of the PDP process.

Additional duties include but are not limited to:

- Develop U.S. and International regulatory strategies for product submissions such as identifying needs for bench, animal and clinical testing
- Prepare U.S. and International submissions as well as work with government agencies and distributors to obtain product approval or clearance
- Educate cross functional and regulatory team members on regulatory requirements and strategies
- Communicate concisely with parties whose primary language may not be English through means such as formal document writing and effective email
- Interact directly with cross functional areas, domestic and international regulatory bodies, and customers
- Research requirements, assemble documentation and write regulatory submissions
- Review ECOs and assess effect of product changes on U.S. and International Regulatory requirements strategy, and submissions per standard procedures
- Employ excellent verbal skills to communicate Regulatory requirements and guidance to product development teams, customers, and upper management

### **Qualifications**

- *Education:* Bachelor's degree in related field.
- *Experience:* 7+ years of U.S. and International medical device regulatory submission/approval experience, to include FDA, JPAL, MDD, PMDA, TGA, and TPD experience
- *Specialized Knowledge:* Knowledge of FDA Quality Systems regulations and ISO requirements. Knowledge of all applicable laws which regulate medical device manufacturers.
- *Special Skills:* Strong leadership, communication and formal technical writing skills. Skilled in management, precision measurement, auditing, training, supplier/customer relations, FDA inspections, and ISO 900

[www.greatbatch.com](http://www.greatbatch.com)

Location: Plymouth, MN

job# 771

Attn: Ann M Reishus, Senior Recruiter