**Part-Time Regulatory Affairs Consultant**

# SCOPE OF SERVICES

Our client is seeking a part time Regulatory Affairs Consultant to assist with the preparation of regulatory submission required to market medical devices in both the U.S. and Europe. Duties include, but are not limited to:

* Represent RA on project teams by providing regulatory guidance throughout the product development cycle, coordinate team inputs for regulatory submissions, and review and approve applicable design control documentation.
* Ensure devices are conformed in accordance with Rapids Quality Management System.
* Support all aspects of International Product Registrations.
* Coordinate and collect specific registration information and develop a Regulatory Plan based off the current Regulatory Strategy.
* Assist in labeling review and approval and obtaining UDI numbers.
* Assist in submitting 510(k) applications.
* Prepare/update technical files for CE marking.
* Submit notifications to the EU and FDA for significant changes.
* Monitor legal and regulatory requirements stated as applicable to Rapid.
* Support special projects, as needed.

The Regulatory Affairs Consultant will work under the supervision of the Director of Quality Assurance and will also support all post-market surveillance activities.

# CANDIDATE QUALIFICATIONS

All candidates should have at least:

* 1 – 3 years medical device experience.
* At least 2 years Regulatory Affairs experience in medical device regulations.
* Demonstrated success in taking products through FDA and EU Notified Bodies.
* Working knowledge of ISO 13485, 21 CFR Part 820, EU MDR 2017/745 and ISO 14971:2019.
* Strong communication and project management skills.
* High-speed internet.