ripple

Regulatory Leader (Medical Device)

Are you hungry to develop new medical devices that have a meaningful impact on people's lives? Do you get frustrated that it takes so long for new technology to move from research labs into the clinic? Are you excited by the idea of using neurotechnology to develop new therapies for people suffering from disability, chronic disease, pain, depression, and anxiety?

Do you have a history of stepping up in your role to bring about positive change? Do you love digging in deeply to plan regulatory strategy? Do you have good working relationships with regulators at FDA and CMS? Have you been the lead author on 510(k) and PMA submissions for electronic devices, active implantable devices, and software as a medical device? Have you successfully overcome what seemed like overwhelming obstacles by thoughtfully presenting a different viewpoint that allowed for a great outcome?

Have you spearheaded interactions with CMS to get new codes approved? Have you helped design and execute clinical trials that have successfully demonstrated to CMS the value of your products? Do you use a machete to cut through red tape?

If this is you, we need you. We need a steady, inspiring leader, with long-range vision to lead our Regulatory team. We need someone with the ambition and drive necessary to help our company get multiple active implantable Class II devices cleared in the next few years. And, in case you like a challenge, we also need help taking a family of sophisticated, external electronic medical devices, with complex software, through a 510(k) submission too! Talk about impact!

Our company has been around for 15 years, with a core focus of translating bio-electric medicine from the benchtop into clinical practice. We have a team of engineers, quality professionals, and production staff who are committed to making this dream a reality. We currently have multiple projects approaching human clinical trials and the funding necessary to take them through premarket submissions. We need a positive, inspiring, sharp, hardworking, passionate, resilient, problem solving, regulatory leader to help us take the ball over the goal line.

To be successful in this job, you will need to be comfortable having an opinion, and be able to communicate it in a collaborative way. You will work directly with our senior leadership team. You will also work closely with our highly experience Quality Leader who is currently driving our push to achieve ISO 13485 certification by the end of the year.

Heads up: We have A LOT of work to do. Currently we are finalizing Pre-Subs with the FDA on several of our implantable projects. We have several IDE submissions under review and several more that we need to draft from scratch. We have plans to submit multiple 510(k)s in the next two years. We will be starting a clinical trial for an active implantable device later this year, with another to follow shortly after.

This is a full-time, exempt position, starting as soon as possible in our Salt Lake City office. This position reports to our CEO Andrew Wilder, CSO Danny McDonnall, and CTO Scott Hiatt (aka the partners of the company) for now, and the position is expected to sit on the executive management team after proven success.

About this Position

Here's what we are looking for. If you have any of the following experience, then give us a holler:

- 10 years professional experience with FDA submission preparation and approvals
- Direct experience with CMS in new code development
- Extremely good communication skills – like, really really good, like the best!
- 5 years professional experience with electronic medical devices
- 5 years professional experience with medical device software
- 5 years professional experience with class II and\or III implantable medical devices
- 5 years professional experience in medical device manufacturing
- Experience preparing FDA submissions (e.g. 510(k), PMA, IDE, 513(b))
- Internal Auditing Experience
- Strong organizational and leadership skills
- High level of creativity and a demonstrable ability to solve complex problems

Here's what you'll do:

- Inspire everyone at Ripple to reach regulatory approvals
- Gap analysis of current projects to market submission
- Lead and participate in IDE, Q-Sub, 510(k) and PMA generation and submission
- Train company in all aspects of Regulatory Compliance
- Help develop culture of the company
- Develop and recruit an excellent Regulatory Team

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. We are a team. We pitch in and help each other on all projects. If you are "above" doing certain tasks, Ripple is definitely not a good fit for you.

Ripple is committed to equal employment opportunities, and does not discriminate on the basis of any protected class defined by the Equal Employment Opportunity laws. Yeah, I know. You've heard it a million times, but we really do mean it. We take pride in having a diverse workplace. We are totally willing to make reasonable accommodations to enable individuals with disabilities to perform this job.

About Ripple

Ripple creates life enhancing neurotechnology for research and medical applications. Our products integrate cutting-edge hardware and software elements designed to read and write from the human nervous system. We are funded by our sales revenue and grants from NIH, DARPA, and the Congressionally Directed Medical Research Program (*sigh* that was a mouthful.)

At its core, Ripple is a community of driven people who are choosing to work together on really hard problems. We are builders and creators and want to see our efforts impact the world for good. Those who thrive at Ripple are self-motivated and work well independently. There are times of intense effort and individual contribution and sacrifice, but we know that what we are building will take time, and living a fulfilling life outside of Ripple will keep team members deeply engaged.

Ripplers are given high-level tasks and a bit of context. Then, they are expected to seek out information, standards, develop new skills and design something great with a team of similarly dedicated and driven colleagues.

At Ripple, team members are often asked to do things they have never done before. We expect a lot of chances to hear differing opinions, and to be surrounded by people who deeply care about our projects and are interested in the big picture of what Ripple is trying to accomplish. Ripplers are encouraged to take time to help and teach others, and to listen, learn and change their own views until a solution emerges.

We expect great ideas to come from everyone at Ripple. We are passionate and friendly, patient and thoughtful, and all agree to not work with jackasses (no matter how great you think you are). All of us must actively contribute to the quality of our processes and products through thoughtful effort. There is no shortcut to making implantable medical devices or cutting-edge neuroscience tools, but with a strong team of friends building them together, it is worth it.

What do you think?
Does this job posting make you warm and fuzzy inside? Are you already on our website checking out our products to see what the fuss is all about?

Then what are you waiting for? Send your resume on over to jobs@rppl.com with a cover letter explaining your interest in this position, and in working for Ripple. Note a cover letter is critical to be considered for this position. Tell us why this job posting spoke to you.

We are excited to hear from you!