



Quality Engineer (Medical Devices)

Do you love Quality, like in that weird way you really can't explain but you just couldn't imagine living without? Does the PA in CAPA make you giddy? Do you dream of a perfect Trace Matrix?

Have you trained a group of engineers and seen their glazed-over eyes brighten a bit as they started to catch the vision you were presenting? Have you personally built systems that people want to follow, not because they have to meet regulations, but because they can see the inherent benefit?

We need you. We have the ambitious goal of taking multiple fully-implantable active Class II/III devices through market clearance in the next few years. And we thought, you know, while we are at it, we should take a handful of very complex high-end external electronic medical devices with really complicated software through a 510(k) submission too! Who doesn't love a challenge?

We have just added a highly-experienced Quality Leader, Mike, to lead our quest to compliance and market clearance. He has a wealth of experience with many types of devices and systems and is constructing the QMS you always wished you worked in. This is not a position that you should expect to step into a ready system and enjoy the ride. We need you to help architect and actively develop this system. We need a Quality Engineer who can translate standards into practices that make sense.

Heads up: We have A LOT of work to do. While Mike is point on completely updating our implementation of ISO 13485 to the 2016 standard and ISO 62304 implementation, compliant to MDD and FDA requirements, ready for submission, scrutiny, audits and certification. We need a Quality Engineer to drive design controls from concept. You will work daily with our engineering teams, seriously dedicated and creative engineers who need your help to capture, verify and validate their designs above scrutiny. We need additional process controls and a full post-marketing system design.

This is a full-time, exempt position, starting immediately in our Salt Lake City office. This position reports to our Director of Quality, Mike Gomez.

About this Position

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

- Required: Medical Device experience in a 13485 QMS (we love you mining, oil and infrastructure engineers, but this position is only for experienced Medical Device Engineers)
- Develops, modifies and maintains quality system procedures supporting a medical device
- Manages and/or performs and supports internal or external audit activities where needed

- Collaborates with operations, manufacturing, engineering and regulatory functions to ensure quality standards are in place
- Maintains and/or Creates Risk Management Documents for Products under Design Control and/or Released Product (includes Risk Management Plan/Report, Risk Analysis Document, Risk Management File, dFMEA, sFMEA and pFMEA)
- Supports new product introduction activities with product design transfer efforts, implementing processes, reviewing and approving plans and reports and supporting qualifications and validations
- Manages CAPA projects using Problem Solving and Statistical Tools while keeping to predefined deadlines
- Devises and implements methods and procedures for inspecting, testing and evaluating the precision and accuracy of products and production equipment
- Designs or specifies inspection and testing mechanisms and equipment; conducts quality assurance tests; and performs statistical analysis
- Provides leadership and review of Process, Test Method Validation and Non-Product Software Validation with cross functional teams
- Supports supplier evaluations and qualifications
- Performs other related duties as assigned
- A bachelors degree in a technical discipline and a minimum of five years practical experience as a Quality Engineer in support of a commercially available Class II/III active implantable medical device or an equivalent combination of education and experience
- CQE and Software design life cycle experience are a plus
- High level of creativity and a demonstrable ability to solve complex problems
- Inspire everyone at Ripple in the virtues of Quality
- Help prepare QMS for 3rd Party Certification
- Help develop culture of the company
- Be thoughtfully constructive: We are looking for solution-oriented team players who can check their egos in order to collaborate to overcome obstacles.
- Genuinely care. At Ripple, we care deeply about each other and treat each other with respect, kindness and patience. We care about the products we create and demand the best of ourselves.
- Believe in Quality! All Ripplers are committed to making everything we build or design exceptional by being proactively involved in the quality process.

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 find value in 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?

Are you into it? Does this job posting make you warm and fuzzy inside? Are you already on our website checking out our products to see what you can do to make them even better?

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.

We are excited to hear from you!