Principal Design Quality Engineer – ME/EE

Department: Quality

Direct Manager: **Donielle Baudin**

Hiring Manager: **Donielle Baudin**

Location Type: Limited-Hybrid

Required Days in Office: 4 Days / week

Work Type: Full Time Salary

Office: Mt. View, CA

Salary: $160,000 – 190,000

Who We Are

At Levita Magnetics, we're not just advancing surgical technology; we're redefining it. Based in the heart of Silicon Valley, we were founded by visionary surgeon Dr. Alberto Rodriguez-Navarro, and our mission is to revolutionize surgical care through innovation and cutting-edge technology.

Our flagship innovation, the Magnetic Surgery® platform, is the first and only of its kind, transforming surgical procedures and improving patient outcomes. In 2023, we introduced the MARS® platform, which builds on the success of Magnetic Surgery® to offer even greater benefits for surgeons and hospitals. If you are driven by innovation and excellence, come help us transform the future of surgery.

About The Team

Join our Quality team at Levita Magnetics, where you'll play a pivotal role in driving innovation and product leadership in minimally invasive laparoscopic surgery. We're a technical, solution-oriented, and accountable team, seeking like-minded individuals to join us. Utilizing a data-driven approach, we tackle challenges and fuel innovation. Committed to exceeding FDA and international regulatory standards, we take initiative, optimize processes, and implement agile quality management systems to foster continuous improvement. Our goal is to make a meaningful impact on patients' lives by setting new benchmarks and breaking

barriers in the field of laparoscopic surgery and medical robotics. Come join us as we shape the future together!

A Day in The Life of Our Principal Design Quality Engineer

This role offers hands-on technical guidance and quality leadership throughout all stages of product development, including technology transfer and commercialization. We seek a highly motivated individual who is a self-starter, team player, and effective communicator.

- Represents Quality in new product development, ensuring compliance with company and regulatory standards.
- Leads and advises on risk management for new and modified products, including developing and authoring plans, reports, and overseeing risk assessments and safety testing (ISO 14971, IEC 60601) throughout the product lifecycle.
- Partners with R&D and Human Factors SMEs for usability assessments (IEC 62366-1).
- Collaborates with R&D to develop verification and validation strategies.
- Ensure timely completion of premarket and post-commercial design changes.
- Provide design and manufacturing documentation, including specifications, drawings and procedures to ensure product manufacturability and evaluation.
- Ensure reliable and scalable designs transferred to manufacturing
- Authors and reviews test methods and test method validations for functional and reliability testing of products.
- Conducts data analytics to evaluate the design and product realization process.
- Independently manage CAPA records and performs timely CAPA engineering tasks, assesses issues, and implement corrective actions
- Performs audits of Design History Files and supports both internal and external audits.
- Assists Regulatory Affairs with submissions and inquiries. Supports field service engineering with nonstandard repairs and serviceability assessments.
- Maintains compliance with Levita Magnetics Quality Management System and promotes best practices in statistical tools and techniques.
- Handles other QMS activities as assigned.

About You

- BS in Engineering (Mechanical, Industrial, Electrical), Life Sciences, or related field.
- 10+ years in medical device engineering or 5+ years with a master's degree, including 3+ years in a Quality role.
- Experience with complex software driven medical electro-mechanical devices (preferred)
- Proficient in 21 CFR 820, ISO 13485, Design Controls, Document Controls, Risk Management (ISO 14971), and Production/Process Controls.

- Risk management (FMEA, Hazard Analysis), GD&T, and inspection methods.
- Use of quality tools and statistical programs (e.g., risk assessment, SPC).
- Design spec interpretation and quality issue resolution.
- Knowledgeable in Design for Manufacturability, Assembly, and Serviceability.
- Experience defining inspection methods and specifying inspection equipment
- Proficient Microsoft Office Suite, ePLM/eQMS systems.
- Self-starter, strong organizational and time management skills
- Effective communicator who delivers clear, impactful messages and drives results
- Certified CQE, CQA (BM), CQM, Six Sigma, etc.(preferred).

Qualified candidates please submit your resume to careers@Levita.com for consideration.