

Principal Design QA Engineer

Job Type : Full- time, Onsite
Location : Mountain View, California

Overview:

Levita Magnetics is transforming minimally invasive surgery through Magnetic Surgery® and its surgical robot MARS™. We operate in a lean, fast-paced environment with a growing pipeline of innovative products.

We are seeking a **Principal Design QA Engineer** to strengthen our Quality & Regulatory team. This role provides hands-on technical guidance and quality leadership across all stages of product development, including design, technology transfer, and commercialization.

Come join a dynamic and highly motivated group aiming to reduce the invasiveness and improve the efficiency of surgery for millions of people worldwide via an innovative combination of magnetics and robotics!

Key Responsibilities:

- 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 manages 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.

Qualifications:

- 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).

The annual base salary range for this position is from 165K-195k.

 Send your resume to talent@levita.com **with subject "Principal Design QA Engineer"**

Benefits may include: medical, dental, and vision insurance, 401(k), paid time off, paid sick leave, and equity compensation. Applicants must be authorized to work in the United States without current or future sponsorship. Employment with Levita Magnetics is at-will.

This position complies with applicable federal, state, and local wage laws.

If you require a reasonable accommodation during the application process, please contact talent@levita.com

Levita Magnetics is an equal opportunity employer. We prohibit discrimination and harassment of any type without regard to race, color, religion, age, sex (including pregnancy, childbirth, or related medical conditions), national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state, or local laws. This policy applies to all terms and conditions of employment.

By submitting your application, you acknowledge that you have read and understood our California Consumer Privacy Act (CCPA) Notice at Collection, which can be found at <https://www.levita.com/privacy>