

## Principal Software Quality Engineer

**Job Type** : Full-time, Hybrid  
**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 Software 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. The position is driven by company growth and the increasing complexity of software development, and will play a key role in bridging current quality systems with software needs.

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:

- **End-to-End Software Quality Leadership**
  - Set and drive the quality strategy for software development, ensuring alignment to Levita Magnetics QMS and global regulatory expectations.
  - Ensures software quality through the development, review, and approval of design V&V protocols and reports, ensuring compliance with design controls and technical standards
  - Serve as the authority on IEC 62304, ISO 14971, and FDA regulations—guiding teams to make sound, compliant decisions without slowing innovation.
  - Own DHF quality and audit readiness; stand behind the integrity of the design and its documentation.
  
- **Risk & Cybersecurity**

- o Lead risk management and cybersecurity as proactive design disciplines—not check-the-box activities.
- o Make clear, defensible decisions on patient safety risk, vulnerability impact, and SOUP usage.
- o Ensure “Security by Design” is embedded in architecture, verification, and release decisions.
- o Define what “good” looks like for software V&V—and hold teams accountable to it.
- o Drive risk-based test strategies, traceability, and defect management to ensure confident, timely releases.
- o Own release readiness decisions, balancing speed with uncompromising quality and compliance.
- **Change Control & Decision Making (SRB)**
  - o Lead Quality decisions for software changes—ensuring the validated state and safety profile are never compromised.
  - o Make tough calls on defect disposition and technical risk, with clear rationale and accountability.
  - o Drive defect dispositioning, determining if software bugs require immediate remediation or can be deferred based on patient safety risk
  - o Own impact assessments, regression scope, and revalidation strategy.
- **Post-Market Quality & Continuous Improvement**
  - o Own software quality in the field—driving CAPAs, assessing complaints, and determining when action is required.
  - o Lead SBOM and vulnerability monitoring to ensure ongoing safety and regulatory compliance.
  - o Support Field Service Engineering with non-standard software repairs, serviceability assessments, and software upgrade
  - o Continuously improve product and process performance through data-driven insights.

**Qualifications:**

- BS in Computer Science, Software Engineering, or related field.
- 10+ years in medical device development (or 5+ with advanced degree), including software Quality Engineering experience.
- Proven track record supporting software-driven medical devices (embedded, standalone, and/or SaMD).
- Deep expertise in FDA and international standards (21 CFR Part 820, ISO 13485, IEC 62304, ISO 14971).
- Demonstrated ownership of software risk management, V&V, and release decision-making.

- Strong technical depth—able to interpret architecture, challenge designs, and resolve complex quality issues.
- Experience with secure software development (cybersecurity, data integrity, privacy).
- Proficiency with modern development and quality systems (eQMS, Jira, Git, etc.).
- A self-directed leader who takes initiative, drives alignment, and delivers results without waiting to be asked.
- Clear, confident communicator who influences decisions and elevates team performance.
- ASQ CSQE, CQE, or Six Sigma certification (preferred).
- Effective communicator who delivers clear, impactful messages and drives cross-functional alignment.
- ASQ Certified Software Quality Engineer (CSQE), CQE, or Six Sigma certification (preferred).

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

 Send your resume to [talent@levita.com](mailto:talent@levita.com) **with subject "Principal Software 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](mailto: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>