Job Description

Position Title:	**Quality Assurance Manager**
Report To:	**Sr. Director Quality Assurance & Regulatory Affairs**
Department:	**QA/RA**
Location:	**Mountain View**
FLSA:	**Exempt**
Date:	**February 2024**

APPLY

We are changing the standard of care for millions of untreated sufferers of ENT conditions. We improve patient access to life-changing relief through safe, practical, and effective innovation that changes how and where patients are served. Aerin differentiates itself with our commitment to providing straightforward and clinically proven products so that ENTs and their patients can make treatment decisions together without limits.

At Aerin Medical our values show up as: always seeking the collective good, holding ourselves and each other accountable, showing respect with compassion, creation and innovation and being all in.

As the Quality Assurance Manager at Aerin Medical, you will be an essential part of our mission-driven team, dedicated to transforming the lives of those with untreated ENT conditions. Your role will involve contributing directly to our commitment to innovation and improved patient care.

Job Overview:
This QA Manager is responsible for maintaining Aerin quality system to meet applicable regulatory requirements. The job scope includes leading and managing supplier quality, CAPA/NCR, complaints, and product returns. This position is responsible for providing quality system expertise to Operations, R&D, contract manufacturer(s) and other departments, as necessary. This person is also responsible for supervising and leading the Aerin Medical California quality group and serving as the site lead for the Aerin Mountain View Office. This person is responsible for ensuring the product complies with Aerin specifications, SOPs, quality requirements and any applicable product standards.

KEY RESPONSIBILITIES:

Manager

- Lead and manage Quality department staff and activities in the Aerin Mountain View Office
- Ensure department personnel are appropriately assigned to cover routine activities and support projects.

Quality System

- Prepare and maintain Aerin quality management system (QMS), SOPs and Quality Manual compliance to ISO 13485, FDA QSR 21 CFR Part 820 and applicable regulatory requirements
- Work with cross-functional stakeholders to establish procedures that meets QMS standard requirements
- Lead external regulatory body audits
- Drive readiness of external regulatory body audits/inspection and closure of findings, if any
- Evaluate product related changes initiated by R&D and/or contract manufacturer. Assist with the development of required documentation or justification to support proposed change.
- Oversee the Supplier Quality/CAPA/NCR/Product Return/Complaint Programs
- Review and maintain post-market surveillance data and files, include tracking of product related NC, CAPA status.
- Drive quality system implementation/improvement projects
- Support validation of eSystems (i.e., eQMS, MRP, eTMF)
- Prepare and conduct QMS related trainings
- Conduct gap analysis of new and revised standards/regulations
- Any other task as assigned

QUALIFICATIONS:

- Bachelor's degree or diploma in Science, Engineering, Quality or similar discipline
- 8 or more years of experience in quality, R&D and/or manufacturing function in medical device industry
- Deep understanding of ISO 13485, EU Medical Device Directive / EU Medical Device Regulations and FDA QSR Part 820
- Preferably with prior experience in manufacturing, product validation, software V&V and/or statistical analysis.
- People Management experience is highly desired
- Independent, high level of initiative and ownership to drive department and organization goals.