# Job Description

Position Title: Quality Engineer

Reports to: Sr. Director Quality Assurance & Regulatory Affairs

Department: QA/RA

Location: Mountain View, CA

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**PURPOSE OF JOB**: This position is responsible for providing quality engineering expertise and feedback to Manufacturing Operations and contract manufacturer(s). He/She is responsible for ensuring Aerin products and processes comply with SOPs, specifications, quality requirements and any applicable product standards. He/She will manage the customer complaint handling program.

**MAJOR DUTIES AND RESPONSIBILITIES:**

- Lead and manage customer complaint handling activities, including report writing, risk assessment, and investigation to timely closure
- Coordinating with Contract Manufacturers on complaint investigations, tracking and monitoring
- Investigate and resolve non-conformance, returned goods, and CAPAs leading to satisfactory closure
- Ensure audit readiness, including:
    - proper segregation and traceability of product and component inventory
    - proper identification of equipment, tools, shelves and product areas
    - completeness of records (e.g. filing of documents, records & certificates)
- Manage equipment calibration and maintenance program
- Conduct internal audit, supplier audits, and support external regulatory body audits
- Perform incoming receiving, inspection, and release of components, subassembly, and finished products
- Ensure customer order, distribution processes, and records (in Oracle system) comply with SOP requirements
- Collaborate with Manufacturing Operations to monitor quality of production and review production Device Master Record
- Analyze quality data and track key quality metrics according to Quality Objectives
- Any other tasks assigned

**EDUCATION REQUIREMENTS:**

- Bachelor's degree in Engineering, Biomedical Engineering, Technical discipline or equivalent

**EXPERIENCE REQUIREMENTS:**

- 2-5 years of quality engineering experience and statistical analysis in medical device industry
- Good understanding of ISO13485, EU Medical Device Directive/Medical Device Regulation, FDA QSR Part 820 and other applicable standards.
- External or Internal Auditing experience and/or certification preferably as a lead auditor, desired
- Prior experience in medical device manufacturing environment

**OTHER QUALIFICATIONS:**

- Excellent interpersonal and communication skills (both verbal and written) that allow for effective communication with all levels of organization
- Demonstrated ability to work well with cross-functional departments and stakeholders in a proactive and constructive manner
- Takes initiative and ownership to drive department and organization goals

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| Employee Name | Signature | Date |
| Supervisor Name | Signature | Date |