Job Description

Position Title: **Senior/Quality Engineer**

Reports to: **Director of Quality Assurance & Regulatory Affairs**

Department: **QA/RA**

Location: **Sunnyvale, CA**

PURPOSE OF JOB: This position provides quality engineering expertise to R&D and Contract Manufacturer(s). He/She is the quality contact point for USA office and is the liaison person between Aerin Singapore, Aerin USA and suppliers. He/She is responsible for ensuring Aerin products and processes complies with SOP, specification, quality requirements and any applicable product standards.

MAJOR DUTIES AND RESPONSIBILITIES:

Quality Assurance

- Participate and support new/modified product development and Operations projects as QA representative, including to:
  - facilitate design input, output and transfer deliverables identified in each design phase
  - support product, process and sterilization validation activities, specification development, test plan/report review and approval
  - assist with justification development to support proposed change
- Point-of-contact for Complaint, Returned Goods Authorization, NC and CAPA and to:
  - facilitate investigation and work with cross-functional stakeholders to resolve issues
  - track status and action plan completion
- Review batch record and authorize finished goods release
- Conduct internal audits
- Perform analysis of post-market surveillance data to support risk analysis update (e.g. Hazard Analysis and FMEAs), Management Review and Quality Objective
- Conduct training and advocate quality system procedures and requirements to Engineering and other departments
- Act as a liaison for Aerin SG team, Aerin USA team & Supplier and facilitate issue resolution and task completion
- Any other tasks as assigned

Audit

- Ensure audit readiness of Sunnyvale site, including:
  - proper segregation and traceability of product and component inventory
  - proper identification of tools, shelves and product areas
  - completeness of on-site record (e.g. filing of documents, records & certificates)
- Support both on-site and remote Notified Body, regulatory agency audit and inspection

Aerin MEDICAL

Job Description

Production & Operations

- Manage Contract Manufacturer (CM) activities, including to:
  - facilitate manufacturing line setup and transfer
  - monitor manufacturing performance and enforce applicable product & process quality requirements
  - conduct routine supplier audits
- Perform incoming receiving, inspection and release of component, subassembly and finished product
- Ensure customer order and distribution processes & records (in Oracle system) comply with SOP requirements

EDUCATION REQUIREMENTS:

- Bachelor's degree or diploma in Science, Engineering, Quality or similar discipline

EXPERIENCE REQUIREMENTS:

- For degree holder, 5 or more years of experience in quality, R&D and/or manufacturing function in medical device industry
- For diploma holder, 8 or more years of experience in quality, R&D and/or manufacturing function in medical device industry
- Good understanding of ISO 13485, EU Medical Device Directive and FDA QSR Part 820
- Internal auditor trained in ISO 13485, ideally with lead auditor certification
- Preferably with prior experience in manufacturing environment, product or process validation, gamma/EO sterilization and/or statistical analysis.

OTHER QUALIFICATIONS:

- Independent, high level of initiative and ownership to drive department and organization goals
- Good problem solving skills
- Proactive and ability to work well with cross-functional departments and stakeholders in a constructive manner
- Excellent interpersonal and communication skills (both verbal and written) that allow for effective communication within all levels of organization