Job Description

Position Title: Quality Engineer

Reports to: Director Quality Assurance & Regulatory Affairs

Department: QA/RA

PURPOSE OF JOB: This position is responsible for providing 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 office, Aerin USA offices and suppliers. He/She is responsible for ensuring Aerin products and processes comply with SOPs, specifications, quality requirements and any applicable product standards..

MAJOR DUTIES AND RESPONSIBILITIES:

- Perform incoming receiving, inspection and release of component, subassembly and finished product
- Investigate and resolve non-conformance, complaint and CAPAs leading to satisfactory closure
- Ensure customer order and distribution processes & records (in Oracle system) comply with SOP requirements
- 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 records (e.g. filing of documents, records & certificates)
- Conduct internal audit, supplier audits, and support external regulatory body audits
- Participate in new product development and support deliverables required for each design control phase
- Evaluate product and process changes initiated by R&D and contract manufacturer and assist with development of required documentation to support change
- Prepare, review, approve and ensure proper documentation of product, process and sterilization validation/verification protocol and reports
- Collaborate with Operations to monitor quality of production and review production Device Master Record
- Participate in FMEA creation and review. Compile and maintain risk management file.
- Analyze quality data and track key quality metrics according to Quality Objectives
- Support management of Contract Manufacturer (CM) activities, including: monitoring contract manufacturer/supplier performance, enforcing applicable product & process quality requirement, and conducting routine supplier audits
- Any other tasks assigned

EDUCATION REQUIREMENTS:

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

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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.
- Trained in ISO 13485 internal auditing, preferably as lead auditor
- Prior experience in manufacturing environment, validation and gamma sterilization is advantageous

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