Position Title: Sr. Supplier Quality Engineer

Reports to: Sr. Director Regulatory Affairs & Quality Assurance

Department: Regulatory Affairs & Quality Assurance

Location: Mountain View Office

PURPOSE OF JOB: This position is responsible for providing supplier quality engineering expertise to R&D, Operations, 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 evaluating suppliers by conducting on site audits, analyzing defect trends, and leading continuous improvement projects. Responsibilities include identifying, investigating, and resolving supplier quality problems. Travel to the suppliers' locations is a must.

MAJOR DUTIES AND RESPONSIBILITIES:

- Visit vendor facilities and observe the manufacturing and distribution environments to review and assess their processes and procedures
- Conduct supplier audits to ensure vendors continue to work in compliance with company and regulatory standards
- Review incoming supplies and finished goods from vendors to check for defects, ensure quality and authorize release
- Investigate and resolve supplier non-conformances, complaints and CAPAs leading to satisfactory closure
- Manage supplier management program, including establishment and maintenance of supplier file and monitoring of supplier performance
- Conduct tests and assessments on products to identify quality issues
- Maintain detailed reports on supplier quality, including defect rates and areas that result in flaws
- Provide technical advice and guidance to suppliers to reduce defect rates
- Conduct internal audits, as needed, and support external regulatory body audits
- Serve as a liaison between our company's senior management and the vendors to identify quality issues and come up with solutions
- Evaluate product and process changes initiated by R&D, Operations, and/or contract manufacturers and assist with development of required documentation to support the changes
- Collaborate with Operations to monitor quality of production and review and authorize release of production Device Master Records and Lot History Records including sterilization records where applicable.
- Create and maintain company process FMEA. Review and maintain manufacturing process FMEA jointly with suppliers.
- Support management of Contract Manufacturer (CM) activities, including but not limited to 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

EXPERIENCE REQUIREMENTS:

- 5+ years of quality engineering experience and statistical analysis in medical device industry
- Good understanding of ISO 13485, EU MDD/MDR, FDA QSR Part 820, risk management (ISO 14971) and other applicable standards.
- Trained Lead Auditor
- Prior experience in manufacturing environment, validation and 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