

Job Description

Position Title: Quality Engineer
Report To: Quality Engineering Manager
Department: QA/RA
Location: Singapore
FLSA: Exempt
Date: September 2023

APPLY

PURPOSE OF THE ROLE:

This position provides product quality engineering expertise to R&D, Operations, contract manufacturer(s) and other departments, as necessary. He/ She is the quality contact point for the assigned Aerin product and is responsible for ensuring the product complies with Aerin specification, SOPs, quality requirement and any applicable product standards.

MAJOR DUTIES AND RESPONSIBILITIES:

Product Design

- Participate/ support in new/modified product development projects or sustaining engineering projects and support deliverables required for each design phase, such as product specification establishment, manufacturing process, sterilization validation activities, test plan/report review and approval.
- Support and provide inputs to product related issues such as non-conformity, complaint, CAPA and supplier CAPA.
- Support finished goods or component release activities as required.
- Provide support in the maintenance of risk management files and product design related risk analysis documents (e.g., Hazard Analysis, dFMEA, uFMEA).
- Provide support in the maintenance of post-market surveillance data and files.

Others

- Perform Internal Audit
- Support external audit readiness preparation.
- Support quality system improvements or implementation projects e.g., quality data monitoring and trending
- Any other tasks assigned.

EDUCATION

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

EXPERIENCE

- 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.
- Prior experience in medical device manufacturing environment.

OTHER QUALIFICATIONS

- Independent, high level of initiative and ownership.
- Good problem-solving skills.
- Proactive and ability to work well with cross- functional departments and stakeholders in a constructive manner.