



Forefront Medical Technology Pte Ltd
35, Joo Koon Circle
6th Floor
Singapore 629110

Job Title: Assistant Quality Manager (Regulatory Affairs)

Duties & Responsibilities:

- Oversee the compliance of ISO and GMP standards and liaising with external auditors on surveillance and recertification audits.
- Develop and implement CE Mark authorization process.
- Ensure regulatory compliance and awareness of all applicable US FDA, China SFDA, Singapore HSA, Canada MDR, Brazil ANVISA and European Country regulations, directives and guidelines.
- Recall of product which does not comply with relevant specifications.
- Train and guide new engineers on GMP compliance requirement, quality assurance systems, and procedures.
- Conducting GMP and internal quality audit in the plants.
- Liaise closely with Production Manager to ensure that code of Good Manufacturing Practices relative to manufacturing, raw materials, in-process and finished goods.
- Maintain and continually improve Quality Management System.
- Ensure the compliance of Cleanroom facility to ISO 14644 and the product microbial level is within the specifications.

Requirements:

- Degree in Science / Microbiology / Engineering with min. 5 years of working experience in medical device industry.
- At least 2 years of quality assurance management experience in medical device industry.
- Knowledge of ISO 13485, ISO 9001, MDD (93/42/EEC) and FDA 21CFR Part 820 is essential.
- Knowledge of Process Validation, EtO Sterilization and ISO 11135 is preferably.
- Experience in renewal or new medical product registration.
- Able to work independently and liaise with all level of staff.
- Effectively bilingual in English and Chinese to liaise with China plant.