

Job Description: Manufacturing Engineer

ROLE

Engineer required to support existing and future implant-medical-device manufacturing lines and systems, daily cleanroom operations and driving a lean, KPI-driven and continuous improvement culture across the department.

Training and particular emphasis will be provided in the areas of medical device textiles and vascular grafting and coating.

This position will involve overseeing the maintenance and calibration of critical equipment-systems. There will be a strong linkage with the Quality Assurance department in supporting the Regulatory and Compliance requirements of an ISO13485 organisation.

The candidate should have a strong background in manufacturing, mechanical, production, biomedical engineering or other related disciplines.

PRINCIPLE RESPONSIBILITIES/DUTIES

The Manufacturing Engineer will be principally engaged in the following tasks:

- Provides support to the manufacturing organization to facilitate efficient operations within the production area.
- Support the development of a KPI-driven Production Management System on site
- Optimize operations utilising Lean, Six Sigma, Value Stream Mapping and Problem-Solving Tools
- Monitors performance of equipment, machines and tools and corrects equipment problems or process parameters that produce non-conforming products, low yields or product quality issues.
- Interfaces with Quality and Research and Development organizations to integrate new products or processes into the existing manufacturing area.
- Support continual improvement in production areas and leads key projects
- Assists in new product transfers from Design into Manufacturing Release.
- Manages IQ, OQ & PQ Validation activities
- Generate validation and test protocols, monitor testing, issue qualification test reports and approve components for use in products.
- Responsibility for management of the Calibration and Preventative Maintenance programs.

DESIRABLE SKILLS & QUALITIES

The successful candidate should possess a Bachelor's of Science degree in Engineering, Biomedical Engineering or related field.

Candidate must be highly motivated and passionate about process development / improvement with strong documentation, oral, and interpersonal communication skills required.

Demonstrated problem solving skills are important.

This position has responsibility to make necessary decisions and/or take action, which is required to carry out job duties