

M3DICINE is seeking the role of Production Engineer.

Duties & Responsibilities

- Work with Penang based contract manufacturer (production and engineering) to ensure work instructions result in the manufacture of compliant product
- Support production activities for new products to ensure they meet or exceed requirements and can be manufactured with high quality
- Provide first point of contact for production on yield, quality and throughput issues
- Perform regular audits to ensure production quality meet the requirements - Audit pilot and manufacturing runs
- Responsible for QA review of Specifications and Technical drawings required by the supply chain for manufacture of new devices
- Analysis of production rejects, identify and rectify root causes of rejects
- Investigate and disposition NCRs in a timely manner
- Check the dimensional accuracy for prototype / pre-production activities
- Maintain documents of all inspections and pilot run measurements
- Manage process controls, establishing schedules for reviewing supplier and quality performance.
- Raising problem reports, Non-Conformity reports, Corrective Action and Preventive Actions to address product quality concerns and/or QMS concerns
- Document all manufacturing criteria, calculations performed, and decisions made
- Maintain successful relationships with Australian based Engineering, Manufacturing and Quality Departments

Requirements

- Based in Penang
- Must have Engineering Qualification or equivalent experience
- 1-3 years or more of experience in Medical Device Manufacturing ISO 13485, FDA 21CFR820 and GMP
- Experience in similar production and logistics roles within a regulated industry
- Must be familiar with Mechanical and Electronic Manufacturing processes (PCBA, SMT, Electronics Assembly, etc.)
- Understanding of GMP, QMS and manufacturing audit procedures
- Documentation/ technical report writing experience
- Problem-solving skills, communication skills (English) and competent user of Microsoft Office essential

Reporting to Head of Manufacturing in Brisbane Australia.

Travel would be involved to Australia.

Please email your resume to Mr. Nayyar Hussain at nayyar@m3dicine.com