Manufacturing Engineer

About Aran Biomedical:

Aran Biomedical design, develop and manufacture implantable medical devices, as an outsource partner to many of the leading, global medical device companies. Our innovative technology focus and biomaterials expertise foster a dynamic culture, which delivers next-generation implantable solutions.

About the Role:

The position requires a proven candidate with a background in providing high-value manufacturing engineering support within a GMP-regulated medical devices industry. Candidates must have a minimum of 3 years of experience in providing process, continuous-improvement and compliance support within an ISO-8 (or higher) clean environment. Due to exciting growth on a number of new product/ technology introductions in 2020, the successful candidate will liaise heavily with cross-functional NPI (new product introduction) teams which can encompass R&D, manufacturing-engineering, maintenance, EH&S, quality-engineering and supply-chain functions. He/ She will work as part of a team to maintain high quality/performance/safety standards on all assigned implant-products. Reporting to the Engineering Manager, the position will be challenging, involve exposure to the latest Tier1-company implant product-designs and will require an ability to work autonomously.

Duties and Responsibilities:

- Provide high-value support to Aran Biomedical's manufacturing operations through daily collaboration with production staff and

supervisors, working with cross-functional colleagues to resolve production floor issues.
- Identify and implement manufacturing projects which improve product quality, reduce lead times and reduce costs.
- Deploy the principles of lean and six sigma in identifying and implementing the optimum areas for improvement in manufacturing operations.
- Assist New Product Introduction (NPI) teams with key input into design-for-manufacturing and product flow/layout development. Take ownership for the execution of process qualification related builds.
- Key member of PFMEA-generation workshops.
- Ownership of IQ, OQ, PQ protocol-generation, execution and reporting.
- Maintain, update and review manufacturing, quality and engineering-related documentation as required – driving and reviewing all Engineering Change Notice (ECN) proposals.
- Assist with training of product builder staff on key operational tasks.
- Enjoy a multi-departmental approach to problem-solving where everyone in Aran Biomedical has a voice and is respected for their input in driving root-cause-analysis reviews.
- Always strive to meet or exceed the expectations of our customers.
- Perform facility-based EH&S, layout or energy-savings projects as required.
- 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. This will encompass NCR and CAPA ownership and resolution.
- Make appropriate decisions daily, using the Manufacturing Manager and Senior Quality Assurance representatives as needed as the final arbitrators on critical quality-related decisions.
- Performs other related duties, as assigned.

Skills and Experience:

- Successful candidate must have a strong track record of execution within in a medical device environment. This role will involve production-support of Tier1-multinational-customer products – and as such, experience is essential.

- A Bachelor's degree in manufacturing engineering, biomedical engineering, quality engineering, or related field and 3 years' minimum experience is required.
- Experience in the areas of medical textile technologies (such as polymer/wire-braiding, weaving, knitting etc) and polymer coating/grafting technologies is desirable.
- Strong familiarity with FDA GMP/QSR; ISO 13485 and medical standards is required.
- Experience of transferring products from design into commercial-manufacturing, is highly desirable
- Solid knowledge of PFMEA development, IQ/OQ/PQ validation is required.
- Candidate must be highly motivated and passionate about meeting production targets with excellent time-management, presentation, communication skills, technical writing skills and organizational skills with the ability to work independently or as part of a team.
- Possess strong analytical skills, with a hands-on approach.
- Project management experience is desirable.