Manufacturing Engineer

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. Aran Biomedical's facility is situated along the Wild Atlantic Way in Spiddal, overlooking the Galway Bay and is just 20 minutes from Galway City by car. As we continue to grow and expand our facilities, we are looking for like-minded people to come and join our team.



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 Manufacturing 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 on a daily basis, 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.

Key Requirements for the role

- 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.