Senior 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.

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.

About the Role:

The position requires a proven candidate with a background in leading high-value manufacturing engineering support within a GMP-regulated medical devices industry.
Candidates must have a minimum of 5 years of experience in leading 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 hold a leadership role in maintaining high quality/ performance/ safety standards on all assigned implant-products platforms.
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 leadership to the manufacturing engineering function on site in
- providing high-value support to Aran Biomedical's manufacturing operations.
- Operate as a direct support to the site's Manufacturing Manager and

- Supervisor and a key voice in providing technical direction to all manufacturing operations staff through daily/weekly production and project review meetings.
- Lead medium-to-large scale cross-functional project teams and projects to successful outcomes.
- Display excellent organisational and project management expertise in addressing short-term and longer-term production floor issues pertaining to quality, cost and delivery metrics.
- Manage, coach and mentor manufacturing engineering and technician resources to foster efficient and cohesive department performance.
- Track and monitor employee performance at routine periods providing review feedback and addressing performance concerns.
- Highlight training and development needs of your team to upper management.
- Deploy the principles of KPI analysis, 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.
- Oversee the execution of process qualification related builds.
- Key input to PFMEA-generation workshops with Quality Assurance department.
- Direct IQ, OQ, PQ protocol-generation, execution and reporting.
- Update and review manufacturing, quality and engineering-related documentation as required – driving and reviewing Engineering Change Notice (ECN) proposals.
- Foster 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.
- Manage facility-based EH&S, layout or energy-savings projects as required.
- Overseeing the management of 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 project completion within in a medical device environment.
- This role is a leadership role within the manufacturing engineering group and will involve the 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 5 years' minimum experience is required.
- People and Project management experience is essential.
- Strong familiarity with FDA GMP/QSR; ISO 13485 and medical standards is essential.
- Experience of transferring products from design into commercial manufacturing is highly desirable.
- Solid knowledge of PFMEA development, IQ/OQ/PQ validation is essential.
- 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 the leader of a team.
- Possess strong leadership and analytical skills, with a hands-on approach.