Senior Process Development 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 Process Development as part of New Product Introduction (NPI) within a GMP-regulated medical devices industry.
Candidates must have a minimum of 5 years of experience in leading new products introduced into a commercial state, leading 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 2022, the successful candidate will liaise heavily with cross-functional teams encompassing 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 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 leadership to the engineering function on-site for product and technology transfer from R&D to manufacturing operations.
- Operate as direct support to the site's Engineering Manager as a key decision maker 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 Process Development engineering and technician resources to foster efficient and cohesive department performance.
- Deploy the principles of KPI analysis, lean and six sigma in identifying and implementing the optimum areas for improvement as part of all NPI into a commercial state.
- Oversee the execution of all Test Method Validations and process qualification.
- Key input to PFMEA-generation workshops with Quality Assurance department.
- 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 driving root-cause-analysis reviews.
- 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.

Key Requirements for the Role:

- The successful candidate must have a strong track record of project completion within a medical device environment.
- This role is a leadership role within the Process Development 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 are essential.
- Strong familiarity with FDA GMP/QSR; ISO 13485, and medical standards is essential.
- Solid knowledge of PFMEA development, IQ/OQ/PQ validation is essential.
- The 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.