

NPI 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 commercial transfer of innovative product-designs within a GMP/FDA/ISO regulated medical devices industry. Candidates must have a minimum of 3 years of experience in the transfer of products and packaging-systems from design-freeze through qualification to commercial manufacturing. Due to exciting growth on a number of new product/ technology introduction, 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 develop and maintain high quality/performance/safety standards on all assigned implant-products. Reporting to the NPI 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

- Contribute to the New Product Introduction (NPI) teams with key input into
 - Scaling, development, and validation of product, and packaging.
 - Equipment procurement and facility layout.
 - Initial capacity planning and identifying production operator needs.
 - Development of production and Quality procedures.
 - Material sourcing and procurement including supplier qualification input
 - design-for-manufacturing and product flow/layout development.
- Take ownership for the execution of process qualification related builds and testing.
- Ownership of IQ, OQ, PQ protocol-generation, execution and reporting.
- Initiate, maintain, update and review manufacturing, quality and engineering-related documentation as required – driving and reviewing 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.
- Coordinate and manage teams in meeting internal and external (customer) quality, timeline and budget commitment in transferring product and packaging designs into fully qualified commercial manufacturing processes.
- Deploy the principles of lean and six-sigma in identifying and implementing the optimum areas for improvement in manufacturing operations.
- There will be a strong linkage with the Quality Assurance department in supporting the Regulatory and Compliance requirements of an ISO13485 organisation.
- Make appropriate decisions on a daily basis, using the NPI Manager and Senior Engineering (NPI, Operations, Quality) representatives as needed.
- Performs other related duties, as assigned.

Key Requirements for the role

- Reporting to the NPI Manager the successful candidate must have a track record of success in a manufacturing environment for a medical device company, a degree in Engineering or related field and 3 years' experience in a medical device engineering role.
- Candidate must be highly motivated and passionate about developing new products with strong documentation, oral, and interpersonal communication skills required.
- The individual must be proficient in Medical Device design principles and material selection with a knowledge of FMEA, TMV, MVP, IQ/OQ/PQ and software validation.
- Possess strong analytical skills, with a hands-on approach.
- Project management experience is desirable.