



NPI Technician

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 supporting commercial transfer of innovative product-designs within a GMP/FDA/ISO regulated medical devices industry. 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 and involve exposure to the latest Tier1-company implant product-designs.

Duties and Responsibilities

- Contribute to the New Product Introduction (NPI) teams with key input into
 - Scaling, development, and validation of product, and packaging
 - Identifying production operator tooling and equipment requirements
 - Development of production and quality procedures and documentation
 - design-for-manufacturing and product flow/layout development.
- Assist in the execution of process qualification related builds and testing.
- Take a leading role in the execution of IQ, OQ, PQ, 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.
- Participate in meeting internal and external (customer) quality, timeline and budget commitment in transferring product and packaging designs into fully qualified commercial manufacturing processes.
- Utilise 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.
- Demonstrate initiative in always working on new devices with the plan of large scale/production manufacturing in mind. Display a passion for continuous improvement and lean-manufacturing approaches.
- Carry out operations as required for the Building & Testing/Inspection within the cleanrooms, R&D Lab and Warehouse areas (as required) including processing, packing, and labelling 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, 3 years' experience in a similar role is desirable.
- Candidate must be highly motivated and passionate about developing new products with strong documentation, oral, and interpersonal communication skills required.
- The individual must be familiar with mechanical engineering principles and material properties with a knowledge of validation an advantage.