NPI 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 an experienced and proven candidate with a background in managing the commercial transfer of innovative product-designs within a GMP/FDA/ISO regulated medical devices industry. Candidates must have a minimum of 5 years of experience in the transfer of products and packaging-systems from design-freeze through qualification to commercial manufacturing.

The successful candidate will be part of an NPI (new product introduction) team of engineers and technicians to work cross functionally with Quality, Operations, Design Services and Materials groups. This position will require an ability to work autonomously whilst providing communication updates to all levels of the organisation including the site Leadership team. Customer-relationship management will be a key element of this role as all product designs are developed by Aran Biomedical in conjunction with customers.

Duties and Responsibilities:

- 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.

- Foster strong collaborative partnerships with technical leads and cross-functional team members to develop accurate transfer roadmaps and timelines.
- Provide regular project status update-presentations to customers and the business
- Drive strong adherence to all stage gate reviews for quality, regulatory and business purposes.
- Lead all life cycle development discussions with internal and external stakeholders and participate in the definition and final agreement of realistic, achievable, and cost-effective product specifications.
- Plan, implement and co-ordinate new product introductions through:
    - 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.
- Support quality system requirements through design control methods, design of experiments (DOE), computer aided design, and failure mode and effects analysis (FMEA)
- Manage and support design verification and validation testing and process validations.
- 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 development and manufacturing environment for a medical device company, a degree in Engineering or related field and 5 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 mechanical design principles and material selection. This position has full responsibility and authority to make necessary decisions and/or take action that is required to carry out job duties.