

Senior Project Engineer

FULL TIME POSITION

The Senior Project Engineer will be focused on new product development from concept through launch. This position will work closely with the product management, design, manufacturing, and quality teams. This person will lead project technical feasibility analysis, planning, execution, and will assist in commercialization while adhering closely to project timeline and budget.

QUALIFICATIONS & SKILLS

- 5+ years of engineering experience, with 2+ years of project/program management experience in a new product development environment, medical device industry preferred.
- Proficient in modeling and drafting in CAD, Creo preferred.
- Proficient in principles and application of FEA.
- Highly skilled in principles and applications of GD&T.
- Strong knowledge of medical materials, specifically implantable materials.
- Experience developing complex orthopedic and spine surgical systems desired.
- Bachelor's degree in Mechanical Engineering (preferred), Biomedical Engineering, or other relevant technical discipline. Master's degree is preferred.
- Self-starter, proactive, and accountable individual able to motivate self and others with alignment to company goals.
- Must lead by example and possess strong work ethics. Strong mechanical/mechanism design aptitudes, and problem solving/analytical skills. Must possess work experience using statistical tools for analysis and sample size selection.
- Design for additive manufacturing (DFAM) desirable.
- Experience working per ISO 13485 and 21 CFR Part 820, specifically as the manufacturer of record of implantable devices preferred.
- Ability to create procedures, work instructions, and forms to ensure compliance with regulatory requirements.

RESPONSIBILITIES

- Conceptualize, design, and prototype surgical systems and implants.
- Focus on new product development from concept through launch.
- Execute and evaluate feasibility studies in preparation for biomechanical testing.
- Create and review material part specifications and bills of materials.
- Collaborate with internal manufacturing partners, contract manufactures, and specialists to optimize designs for manufacturability.
- Support IMSE, and the development of its products, through on-site and off-site meetings, trade shows/society meetings, and educational events. Travel as needed.
- Must be able to specify precise new product functional requirements. Design, test, and integrate components to produce final designs. Evaluate overall effectiveness, cost, reliability, and safety.
- Participate actively with Marketing and Sales to define customer needs. Engage surgeons and KOL throughout the conceptualization and development phases. Lead development sessions and actively participate in cadaver labs with surgeons to obtain critical project input.
- Participate in risk management activities (e.g. dFMEA, pFMEA) and lead design activities such as Design Input, Design Output, Design Verification, Design Validation, and Design Transfer (Ex. Mechanical Testing, Cadaver Lab, etc.)
- Responsible to perform the Design Reviews and create the Design History Files documentation.
- Support Regulatory submissions, such as 510(k), from a technical standpoint.
- Assist Quality/Regulatory in review of complaint and non-conformance. Support technical investigations including non-conforming material and CAPA.
- Develop novel innovations for inclusion in IP Portfolio. Support in the launch of NPD projects with Freedom to Operate. Perform assessment of competitive landscape in support of projects, development pipeline, and competitive library/matrix.