

Sr. Product Development Engineer, Medical Device Development

- Description:** The purpose of the role Sr. Product Development Engineer is to manage product development projects and perform engineering tasks to develop medical devices per customer needs.
- Initial design concepts as required by user needs,
 - Build and maintain project schedules and budgets,
 - Complete technical and QMS documentation including engineering drawings and risk management activities,
 - Develop and execute technical protocols and reports for design verification and validation activities,
 - Manage assigned projects including resources, timelines, and budgets, and
 - Build parts and complete testing as needed to execute engineering activities.
- Qualifications:**
- University degree in Biomedical or other engineering discipline and 7+ years' experience in a medical device research, development and manufacturing,
 - Knowledge of human anatomy and physiology,
 - Knowledge of commonly-used manufacturing methodologies and the science behind them,
 - Ability to use hand tools and light or industrial equipment,
 - Ability to make accurate measurements, and
 - Oral and written technical communication skills.
- Report To:** Engineering leadership [TBD]
- Subordinates:** None
- Skills**
- Design controls – 21 CFR 820.30, ISO 13485.
 - Risk Management – ISO 14971.
 - Design validation.
 - Time and resource management.
 - Broad computer skills – CAD, project management software, ERP.
- Responsibilities:**
- Manage product development projects by building schedules, assigning tasks, executing tasks, and communicating with stakeholders.
 - Research engineering solutions to satisfy customer product requirements.
 - Create testing protocols and reports and validate test methods as needed.
 - Complete required QMS activities including risk management, CAPA, FMEA and other related activities.
 - Create and modify CAD models and drawings using appropriate software such as Fusion360 or SolidWorks.
 - Use time management skills to balance multiple projects and communicate estimated completion dates.
 - Apply welding, assembly, testing, and other product manufacturing capabilities to produce prototypes.
 - Comply with all safety and regulatory requirements.