



Helix Medical LLC is a dynamic, innovative, growth-oriented Company specializing in the design, manufacturing, marketing and sales of silicone medical devices and components. In keeping with our commitment to excellence, our environmentally controlled manufacturing facilities and quality systems are certified to ISO 13485 requirements.

We are seeking a highly technical **Product Development Engineer** to work as a cross-functional team member in the creation of new medical devices from prototype through final production launch. Applicants should be very comfortable developing and implementing medical device products while providing technical expertise to manufacturing for existing products. This position reports directly to the Engineering Manager. This is an excellent opportunity for the right candidate; however, you must be motivated and THRIVE in a fast-paced environment striving for continuous improvement.

Essential Functions and Basic Duties

- Applies a broad knowledge of principles and practices of engineering in the development of medical devices.
- Leads one or more product development projects for medical devices to achieve on-time results and according to plan
- Provides technical input for projects at all stages of the product life cycle.
- Conducts design verification at various stages of the design process to ensure consistency between the outputs against the requirements
- Maintains Project management and documentation of design controls, risk analysis, etc in accordance with established SOPs.
- Creates performance and functional requirement specifications to comply with ISO standards
- Prepares design layouts and detailed drawings in support of assigned technical activities
- Assesses new technology and new product ideas for technical and economic feasibility, best practices and methods and latest materials, procedures, and criteria as it applies to the specific product.
- Designs test apparatus, equipment and develop procedures for testing products including acceptance and rejection criteria
- Builds and tests prototype devices
- Selects materials for medical devices
- Provides engineering support for products launching to production and resolve issues as they arise.

Qualifications

- BS in Mechanical or Biomedical Engineering
 - 5 to 7 years of experience designing and developing silicone and/or plastic products from concept through production. Medical Device experience preferred.
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- Must have experience in a structured regulatory environment with advanced quality systems such as ISO13485, AS9100, TS16949 or equivalent.
 - Green Belt certification in Lean or Six Sigma desired.
 - Thorough working knowledge of Solidworks and AutoCAD software, 2D& 3D.
 - Working knowledge of MS Project or Project Management experience
 - Must demonstrate ability to work independently and with others in a fast-paced, results oriented environment
 - Excellent communication and interpersonal skills to interact with surgeons, engineers, other team members, machinists etc.
 - Strong mechanical and problem solving skills

In exchange for your skills and talents, we offer a competitive salary plus a full range of benefits including medical, dental & vision insurance, basic & supplemental life, long term & short term disability, and our 401K currently has a company match that is 100% vested after 2 years.

More importantly, you'll become a key player at a rapidly growing medical device engineering and manufacturing company. If you're like the majority of the people who work here, this will be the best place you'll ever work. Want to learn more about Helix Medical? Check out our website at <http://www.helixmedical.com>. This position is full-time, onsite in Carpinteria, CA.

Interested candidates meeting these qualifications should apply and send a resume and cover letter explaining why you are that one special candidate to helixcareers@helixmedical.com.

Subject: **Job Code PDE#1005H.**

Helix Medical is an Equal Employment Opportunity Employer.