



With more than 50 years of combined experience, Helix Medical LLC is a leading global supplier of medical devices supporting the ENT marketplace and custom manufactured solutions supporting top medical device manufacturers in pharmaceutical, biotech, and medical industries. With operations spanning North America, Europe, and Asia, we are positioned to meet the needs and expectations of our customers. Come join our amazing and inspiring team!

We are seeking a **Medical Device Development Specialist** is a member of a cross-functional team that is responsible for identifying, developing and launching new products to satisfy unmet customer needs for products in the ear, nose, throat, head and neck surgery (ENT/HNS) market segments. Emphasis is on providing value-added solutions to customer needs. The incumbent is the primary interface with the customer on new applications in the early stages of a project when the product is not well-defined. He/she combines his/her knowledge of human anatomy and technical/mechanical skills to bring definition to the product, and support to the product development process, resulting in a flawless launch of new products to the market. This position reports directly to the General Manager, InHealth Technologies. 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

- Provides technical leadership to Sales and Marketing in the identification and validation of new product opportunities. Provides support to the cross-functional team for new product launches on a global basis.
- Translate opportunities for new ENT/HNS products and applications into documented Device Definition Specifications, detailed enough to begin early stage testing and product development. Network with and build close relationships with surgeons, clinicians and key opinion leaders at existing and new strategic accounts to develop them as advocates for our products.
- Provide technical and clinical input and support to the product development process and manufacturing processes to achieve a flawless and on-time product launch.
- Acts as a liaison during pre-clinical and clinical trials; provide clinical feedback to the product development process.
- Coach, mentor and develop cross-functional teams on the application of ENT/HNS solutions and interfacing with surgeons and clinicians.
- As part of the cross-functional team support regulatory submissions to obtain timely approvals and speed-to-market.
- Supports quality systems and regulatory compliance.
- Supports continuous improvement activities.

Qualifications

- Bachelors Degree in engineering or biomedical/biological sciences and 10+ years of medical device or healthcare industry experience or Masters Degree in technical, science or biomedical engineering and 7+ years of medical device or healthcare industry experience.
- Demonstrated knowledge of human anatomy and physiology.
- Demonstrated understanding of complete life-cycle of products from concepts to production launch.

- Ability to synthesize medical information into meaningful verifiable mechanical or electrical specifications, requirements and recommendations.
- Comfortable working in an operating room and interfacing with surgeons and clinicians.
- Working knowledge of medical device industry ISO, FDA and CE regulations with Class I, II or III medical devices.
- Detail oriented without sacrificing a broad strategic perspective with ability to solve problems or provide technical information or detail for possible solutions.
- Experience in working with cross-functional project management and engineering teams.
- Strong networking, teambuilding and interpersonal skills.
- Excellent technical writing and communication skills, including presentation skills.
- Experience using Microsoft applications: Word, Excel, PowerPoint, Project, etc.
- CAD experience with solid modeling software, i.e. SolidWorks or AutoCAD.
- Ability to travel up to 70%; including international travel.

Preferred Qualifications:

- MBA and/or strong business acumen; strategic thinking and tactical marketing skills.
- Experience with financial analysis methodologies documenting business cases for medical device opportunities.
- Experience with medical devices related to ear, nose, throat, head and neck surgery (ENT/HNS).
- Operating room (OR) experience.
- Experience in the design and manufacture of elastomeric and thermoplastic components and assemblies for medical devices using a Design for Six Sigma (DFSS) approach.
- Experience in lean manufacturing methodologies.
- Field sales or sales/marketing management experience is a plus.

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 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> 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 MDDS#1006H.**

Location is negotiable, preferable relocation to Headquarters in Carpinteria, CA

Helix Medical is an Equal Employment Opportunity employer. "