



**COMPANY PROFILE**

Helix Medical LLC is a dynamic, innovative, growth oriented Company specializing in the design, manufacturing, marketing and sales of silicone based medical and biotechnology devices and components. We are a global leader in the medical device industry with 20 years experience that is focused on silicone medical devices and components. We excel in custom device/component manufacturing for large Medical Device customers and also manufacture and market our own line of products for the Pharma/ Biotech industries.

**POSITION TITLE**

**Product Development Engineer**

**BASIC FUNCTION**

Performs engineering work in the design and development of new products for InHealth Technologies and Helix Medical. Understands and incorporates required regulatory standards ( FDA, ISO, and CE ) in developmental projects including written protocols, test methods, and assembly processes.

**PRINCIPAL ACCOUNTABILITIES**

**Product Development:**

Responsible for design, development, and documentation (including device master files and device history records) of new or modified products on a timetable assigned by VP Research and Product Development.

Measurement: 50%

- Number of designs offered
- Number of product development files created
- Number of prototypes produced
- Number of Design Control Files created
- Number of Device History Records created
- Number of Device Master Records developed
- Number of Design History Files completed
- Documentation at Helix standard
- Number of products released for production as scheduled

Generate product, packaging, and assembly drawings for products and any associated manufacturing or testing jigs and fixtures.

Measurement: 25%

- Number of drawings developed
- Number of packages developed and documented
- Number of test jigs and fixtures developed
- Completed on schedule

**Project Management :**

Propose, schedule, direct, and assist with activities in the execution of defined project objectives.

Measurement: 15%

- Performance against schedule.
- Approval of DHF per schedule
- Support of 510(k) submissions
- Support of Audits

**New Product Identification:**

Maintain awareness and report recommendations on new technologies, customer needs, and business developments in markets where IHT and Helix competes.

Measurement: 5%

- Reports recommending further investigation for business opportunity

**Technical Development:**

Pursue and share technical and/or regulatory education through training seminars and/or classes with approval of the VP Research and Product Development.

Measurement: 5%

- Satisfactory course completion and/or report

**JOB STANDARDS:****Essential function**

Good writing and verbal communication skills.

Ability to use computer programs for word processing, spreadsheets, statistics, project scheduling, and drafting.

**Physical requirements**

Sedentary Work: Position involves sitting most of the time. Standing and walking are required occasionally. Position requires ability to exert minimal force of up to 10 pounds occasionally and minimal force to carry, lift, push and otherwise move objects frequently.

Walking: Physical ability to move about on foot to accomplish tasks related to the position.

**Experience, education or skills**

College degree in Science or Engineering and a minimum of 5 years experience in medical device product development.

**This job description is not intended to be all-inclusive and still takes into consideration routine tasks in your basic function. An employee may also perform other reasonable related business duties as assigned by immediate supervisor or management.**

Please reference job code: PDE2008

Submit your resume to:

Helix Medical, LLC  
Attn: Career Opportunities  
1110 Mark Avenue.  
Carpinteria, CA 93013  
Fax (805) 566-3887  
Email [careers@helixmedical.com](mailto:careers@helixmedical.com)