



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 **Quality Engineer** who will support product quality by establishing quality standards, supporting and facilitating corrective action requests, implementing mistake proofing, developing workmanship standards, creating IPQC documentation, tracking and analyzing internal quality performance, and supporting quality system requirements. This position reports directly to the Director of RA/QA. 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**

- Maintain the InHealth Medical Device Product Complaint System
- Initiate product complaint reports upon receipt of complaint information from customer, clinician, healthcare facility, etc
- Perform and document technical evaluations of returned product.
- Provide support for FDA Medical Device Reporting, EU Vigilance reporting, and Recall activities
- Communicate complaints received to IHT sales force and educational specialists
- Communicates complaint findings to customer base
- Facilitate and support HMI customer complaint resolution including root cause analysis, corrective action, preventative action, and mistake proofing implementation.
- Provide engineering support regarding product testing, failure mode investigations, reliability studies and supplier quality issues.
- Participates cross-functionally as a quality representative for all new product launch activities including all advanced quality planning, mistake proofing, and IPQC creation.
- Assists in engineering and implementing methods and procedures for inspecting & testing; develops and validates measurement test methods; and creates and approves design control documents to assure new products meet guidelines.
- Provides support for internal and external quality audits.
- Communicates significant issues or developments identified during quality assurance activities and provides recommended process improvements to management.
- Participates in the management of the CAPA program and creates monthly CAPA reports.

- Participates as an internal auditor.
- Champion process validation program for the site, as required. Instrumental in establishment of the Validation Master Plan, implementation of the plan, and ongoing maintenance of the plan. Develop, review, and approve process validation reports.
- Provides document change order support.
- Facilitate and participate in Material Review Board activities.
- Identify and implement opportunities for continuous improvement.

### **Qualifications**

- Bachelor's Degree in Engineering, Chemistry, Biology or related science/technical field.
- Three to five years related experience and/or training working knowledge of 21CFR820 (quality systems regulation/good manufacturing practices for medical devices) and ISO 13485 standards.
- Understanding and technical leadership and guidance with statistical techniques (i.e. sample size determination, DOE, Lean and Six Sigma process improvement techniques, etc.)
- Knowledge and understanding of quality requirements for the medical device industry with general technical understanding of business operations.
- Excellent verbal, written, analytical, computer and interpersonal skills with the ability to demonstrate lead capabilities with team approach, and sound decision making.
- Organizational, prioritization, and presentation skills required.
- Previous CAPA experience to include review for risk analysis, correction, preventative action, and closure of CAPA issues.
- Detail oriented without sacrificing a broad strategic perspective with ability to solve problems or provide technical information or detail for possible solutions.
- Works well in a team-oriented, cross-functional environment
- Ability to handle multiple tasks and operate in a fast-paced manufacturing environment
- Excellent technical writing and communication skills, including presentation skills.
- Experience using Microsoft applications: Word, Excel, PowerPoint, Project, etc.

### **Preferred Qualifications:**

- American Society for Quality CQE (Certified Quality Engineer) preferred but not required
- Experience with injection molding, silicone, and coating preferred

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](mailto:helixcareers@helixmedical.com). Subject: **Job Code QE#1006H**. This position is full-time, onsite in Carpinteria, CA.

Helix Medical is an Equal Employment Opportunity employer.