



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 **Director of RA/QA** to lead Quality System, ISO-13485, FDA, MDD 93/42/EEC, MDD Amendment 2007/47/EC, and Medicare compliance. Applicants should exhibit solid RA/QA knowledge, excellent leadership skills, strong communication skills, and a passion for results. This position reports directly to the VP & General 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**

- Responsibility as a management representative will include liaison with external parties on matters relating to the quality management system.
- Develop and implement internal Quality/Regulatory documentation processes to meet FDA & ISO and other regulatory compliance requirements.
- Develop and implement a cross functional internal audit program/team to ensure all regulatory requirements are met.
- Lead and provide expert advice in the areas of compliance QSR, ISO13485.
- Monitor and report on all regulatory compliance activities within the business units.
- Lead assigned due diligence and new business integration activities as required.
- Develop QMS initiatives to drive simplification and standardization throughout the organization.
- Manage overall coaching, training, development and succession plans for the regulatory and quality assurance teams.

### **Qualifications**

- BS in Science or Engineering and Lead Auditor certification or ASQ Professional Certification
- 5 years minimum manufacturing background in medical device or pharmaceuticals.
- 5 years management experience in dealing with FDA and other regulatory bodies.

- Excellent communication skills.
- Ability to effectively interface interdepartmentally.
- Perseverance in investigating alleged non-compliance.
- Effective organizational, technical and problem solving skills.
- Computer skills in word processing, spreadsheets, and databases highly desirable.
- Proven success with FDA and Notified Body interface.
- Understanding of the internal Quality Management System, United States Quality System Regulation (21 CFR 820), the Medical Device Directives, ISO 13485, CAN/CSA-ISO 13485 and all other applicable medical device regulations.
- Experience and demonstrated understanding of quality assurance in a medical device manufacturing and sales environment.
- Experience with silicone or rubber processing highly advantageous.

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>. This position is fulltime, 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](mailto:helixcareers@helixmedical.com).

Subject: **Job Code DoRA/QA#1005H.**

Helix Medical is an Equal Employment Opportunity Employer.

**Agencies & Direct Placements:**

Helix Medical LLC practice is to partner and work with our approved vendors only. Any resumes submitted from unapproved vendors will be considered unsolicited, and Helix Medical will not be obligated to pay a referral fee.