



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 **Project Manager** who will be responsible for managing new prototype development projects, and new production launches using established Advanced Product Quality Planning (APQP) project management practices, with the goal of flawless launch of new products to production. Project leadership is provided for all product lines manufactured at this location of Helix Medical including proprietary products for InHealth® Technologies as well as products for the HelixMark® and Custom Manufacturing Services (CMS) segments.

This position is also responsible to lead new product cost-estimating and team feasibility reviews for activities in support of quoting new business opportunities. Responsible for the management and coordination of the cost estimating team functions for assigned product families in support of new business opportunities. This responsibility includes conceptualizing and defining new and/or modified processes and equipment and developing accurate manufacturing costs. He/she provides the accurate and timely recommendations of proposed processes/equipment and costs, participates in the selection and development of strategic production partners as well as input in the “make or buy” decision process.

This position reports 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

- Provides leadership to manage multiple projects and production launches using established Advanced Product Quality Planning (APQP) project management practices.
- Leads cross-functional teams of resources, drawing from other functional areas, to ensure on-time delivery and a flawless launch to production utilizing ARAS and IPQC best-practices.
- Provides leadership to comply with, and maintains documentation in accordance with Helix Quality System Requirements (QSR), FDA cGMP, internal procedures, customer requirements and notified body requirements.
- To develop accurate and timely manufacturing costs in response to customer or internal inquiries; works with finance to create new work center costs as needed for cost calculations.
- To manage the team feasibility quote process and to challenge, motivate, and evaluate team member performance for assigned product families.
- Oversee the “make or buy” decision process.
- Measures, reports, and continuously improves performance metrics (KPIs) of the product development and launch process.
- Assists in development of design standards, cost standards and pricing standards to expedite and provide input for continuous improvement of the quote process.
- Maintains adherence to Company policies, safety/ergonomic standards and good housekeeping practices.
- Supports continuous improvement processes as required.

Qualifications

Education/certification

Bachelor's degree in a related technical field such as Mechanical Engineering, Chemistry or Plastics Engineering or ten (10) years of directly related experience

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Required Experience:

- 5 years minimum of related experience in a regulated manufacturing environment, preferably medical or healthcare products

Required Knowledge:

- Demonstrated experience providing leadership, managing multiple projects of medium complexity. Proficient in MS Project.
- Working knowledge of ISO-13485 and FDA cGMP regulations
- Experience in advanced engineering/statistical problem solving methods is required. Six Sigma Green Belt certification is a plus, including Design of Experiments (DOE).
- Strong business and economic acumen
- Proficiency in basic computer skills (Word, Excel, PowerPoint, etc.) Working knowledge of ERP/MRP software.
- Ability to understand engineering drawings (including Geometric Tolerancing & Dimensioning). A working knowledge of tool designs, rubber compound characteristics, as well as transfer/injection press mechanics is a plus
- Working knowledge of engineering terminology, extrusion and injection molding processes, tooling and validation protocols.
- Working knowledge of work centers, cost structure, and basic industrial engineering practices.
- Strong interpersonal, oral and written communication skills with the ability to effectively communicate with all levels of the organization, customers and suppliers.
- Must have high personal competency levels in Business Astuteness, Customer Responsiveness, and Focused Urgency.

Preferred Qualifications:

- Degree in biomedical or biomechanical engineering is preferred.
- A working knowledge of Process Failure Modes and Effects Analyses (PFMEA). A working knowledge of Value Analysis/Value Engineering (VA/VE) is a plus
- Business degree or progress toward a business degree
- PMP Certification in Project Management
- APICS certification
- Experience using QAD MFG/Pro ERP software
- Prior experience in a product cost-estimating role
- Lean Systems or Six-Sigma Green Belt Certification is a plus

Required Skills/Abilities:

- Strong business and economic acumen
- Strong interpersonal, oral and written communication skills with the ability to effectively communicate with all levels of the organization, customers and suppliers.
- Good organizational skills
- Accurate and attention to detail.

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 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: PM1005H**.

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.