



COMPANY PROFILE

HELIX MEDICAL, LLC **Careers**

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

Process Development Engineer

(Extrusion, Molding, and Assembly)

Qualifications:

- Bachelor of Science in Engineering or closely related technical discipline is required. Non-degree holder must have at least eight years of related processing experience and a commitment to complete a Bachelors degree in Engineering.
- Three or more years of experience in rubber extrusion, compression, transfer, and injection molding processes and equipment is required. Plastics experience is acceptable but LSR expertise is preferred.
- Three or more years of experience in applying lean manufacturing concepts, statistical process control, and continuous improvement plans. Statistical background and Six Sigma certification is a plus.
- Demonstrated knowledge of troubleshooting techniques, root cause analysis, design of experiment, and data driven corrective and preventive action plans.
- Working knowledge of extrusion, molding, and automated assembly equipment, including PLC-driven electric, hydraulic and pneumatic systems. Experience in a clean room environment is desirable.
- Strong technical ability in reading prints and drawings, mold designs, and process documentation. CAD, 3D solid modeling, and GD&T training are a plus.
- Familiarity with visual measurement system or any applicable metrology equipment is preferred.
- Proven experience with managing complex engineering projects is required. Able to manage multiple projects with conflicting priorities. Familiar with project management and spreadsheet software.
- Excellent communication skills, and highly motivated to complete tasks in a timely fashion.

Responsibilities:

- Provide technical assistance and engineering support to the manufacturing floor, which includes extrusion, molding, assembly, and packaging areas to ensure timely delivery of product that meets customer expectation. Work with other support departments to maintain on-time delivery goals.
- Train production operators, lead process technicians and direct maintenance personnel in resolving process, material, mold, fixture, tools, dies, and equipment problems using systematic methods of troubleshooting, root cause analysis, and irreversible corrective action implementation and documentation.
- Develop, setup, and document new products and processes that will enhance profitability through lean manufacturing concepts, lessons learned, and utilization of available technical support groups.
- Support accurate and on-time response to customer RFQ's and new product flawless launch activities by actively participating in cross-functional team feasibility commitment efforts, design reviews, MRP-based manufacturing cost calculation, FMEA, and APQP process.
- Use GROWTTH methodology to complete projects that meet takt time, eliminate waste, and lead continuous improvement efforts in quality, efficiency, and productivity.
- Develop and execute validation protocols (IQ/OQ/PQ) for new equipment and processes, as well as periodic re-validation of existing equipment and processes

- Prepare, execute, and revise documentation necessary to complete shop work orders such as: FAIR, QCIC, SOP, MP, DCN, EO, BOM, and other work instructions per FNGP, FDA, KEMA, ISO, and external customer requirements.
- Lead projects to timely completion by utilizing project management tools in establishing timelines, assigning responsible persons, and highlighting milestones.
- Establish process flow, calculate takt time, perform time studies, validate processes, conduct process capability studies, execute DOE's, and perform other functions to produce profitable product.
- Utilize good verbal and written communication skills when reporting project status to management or project teams, and during interface with both customers and suppliers.
- Promote adherence to company policies and standards on 5S, safety, ergonomics, and housekeeping.

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: MPDE2008

Submit your resume to:

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