

About the Job

We are currently seeking a Quality Engineer to join our team in designing new Medical Device products. This individual will work with a small team to design, validate, and release new FDA Class I and Class II medical devices.

Responsibilities

- Design fixtures required for manufacturing and inspection.
- Develop inspection methods to analyze product quality.
- Support, maintain, and document device manufacturing processes.
- Improve product quality by making recommendations for change.
- Create and maintain fabrication and assembly drawings related to current and future medical devices.
- Develop and implement safety and efficacy tests for quality assurance.
- Implement a working system to ensure conformity and accuracy in the production process
- Ensure products adhere to company and industry quality standards
- Formulate a strategic plan to increase quality and productivity in the business
- Document test reports and FDA design specifications related to ISO and CE Mark requirements.
- Document results and findings after engineering inspections are carried out
- Work collaboratively in a cross-discipline team environment to improve products
- Collaborate with other departments to produce solutions for identified problems

Required Qualifications

- B.S. degree (BSME is strongly preferred) with 0 - 2 years of experience in mechanical or biomedical engineering
- Strong analytical and problem-solving skills
- Experience in a quality assurance environment is a plus
- Knowledge of material properties and manufacturing methods for low and medium volume production processes.
- Experience with solid modeling using Solidworks is a plus.
- Experience with FMECA and risk management procedures is a plus.
- Experience with ISO or FDA documentation requirements is a plus.
- Excellent verbal and written skills are required.
- Able to work efficiently in a team environment
- High proficiency in MS Office Software (i.e Word, Excel, PowerPoint, etc.)

Company Description

TZ Medical develops products for the Electrophysiology (EP), cardiac and critical-care communities. Over the years, TZ Medical has built a solid reputation on both listening to and understanding the needs of medical professionals. The result is optimal solutions delivering quality products that improve patient care while protecting the administrator's bottom line.

TZ Medical's corporate headquarters are located in Portland, Oregon, with sales and support functions nationwide. TZ Medical is proud to be part of Premier Inc., a hospital performance improvement alliance with over 1,700 participating not-for-profit hospitals and health systems serving communities across the country.

TZ Medical products and solutions can be found in hospitals, critical-care clinics and medical offices worldwide. Our commitment to excellence with the products we manufacture and the services we provide is underlined by our commitment to the medical professionals who use them. This commitment, combined with our passion for life-saving innovation, is what makes TZ Medical. For more information, please visit: www.tzmedical.com.

Benefits Summary

We offer a competitive benefits package including health, dental, 401k, etc.