



MECHANICAL PROJECT ENGINEER POSITION PROFILE

COMPANY OVERVIEW:

OrthAlign, Inc. is a privately held medical device company that was established in the summer of 2008 and based in Irvine, CA. The company is developing a line of computer assisted surgical devices that distill the critical features and benefits of large surgical navigation systems in a non-invasive, disposable, palm-sized solution with accompanying instrumentation. OrthAlign's goal is to create a new standard of care in total joint replacement, making consistent and measurable results accessible to surgeons and patients.

OrthAlign, Inc., is in the phase of confirming the practicality of the technology, the applicability to the surgical suite and is bringing the first generation of products to market. Initial prototypes have been received favorably by leading orthopedic surgeons in the US. The company expects to start commercialization of its first products in the first quarter of 2010.

R&D MECHANICAL ENGINEER:

OrthAlign is currently seeking a Mechanical Project Engineer, who will report to the Director of Engineering/Operations and be a member of a small lean R&D team which utilizes outside services to supplement internal capabilities. The Mechanical Engineer will work in product design and development functions and provide engineering support to the corporation's technological planning and development, working closely with surgeons and marketing group to analyze and define customer needs. Using your prior product development and technical background in Class II - III medical devices and experience with instrumentation used in orthopedic joint surgery, you will work in mechanical design, and medical materials technology to develop complex designs and manufacturing process for novel surgical products. The ideal candidate will work well in a flexible and start-up company environment. Candidate will possess the knowledge and experience of working with outsourced resources in a lean organization.

PERFORMANCE OBJECTIVES: To achieve the mission for this position, the Mechanical Project Engineer must produce the following critical actions and results:

Initial Deliverables:

1. Support design improvements for current products.
2. Assist in verification and validation of current products.
3. Provide engineering support during production transfer.
4. Support sales and marketing during product launch.

Ongoing Deliverables:

1. Work closely with our key target audience: orthopedic surgeons and internal marketing and QA departments to create designs for new products, product revisions, components, assemblies and/or tools.

4. Document engineering work in compliance with the company's quality system.
5. Coordinate activities and work closely with the company's outsources resources, such as a contract manufacturer and/or machine shop.

BACKGROUND AND EXPERIENCE REQUIREMENTS: The ideal candidate will have the following education, work history, knowledge and skills:

- BS in Mechanical Engineering, Biomedical Engineering, or equivalent. Masters preferred.
- Minimum 5 years of experience in medical device design, development, and commercialization.
- Experience in design of orthopedic instrumentation.
- Experience in design of high volume electro-mechanical assemblies.
- Superior design skills and ability to work in SolidWorks environment.
- Track record of working well with surgeons and turning their ideas into impressive engineering outcomes in a small company environment.
- Large joints experience. Knowledge and hands-on experience with total knee and hip replacement systems is desired.
- Ability to work in cross functional teams
- Possess analytical & problem solving thinking skills
- Ability to develop and write test protocols and IQ/OQ/PQ\ and conduct verification testing
- Knowledge of FDA and ISO GMP and design control regulations
- Knowledge of mechanical design and/or machine shop experience
- Experience working with external development and manufacturing resources.
- Excellent analytical, problem solving and organizational skills
- Excellent organizational, documentation and written/verbal communication skills
- Willingness to travel

PERSONALITY AND CHARACTER:

The ideal candidate will have most of the following traits:

- Passion for success
- Customer driven
- Projects confidence and competence
- Team player