TOTAL JOINT ORTHOPEDICS

RESEARCH ENGINEER

The Job:

The Research Engineer is a position for an independent thinker requiring minimal supervision who is experienced with product development, validation, manufacturing and product maintenance in an FDA regulated environments. This position will be responsible for the technical content of validation reports, justification memos, reviewing cleaning, packaging and sterilization requirements and drafting Letter's to File and 510(k) submissions. Additionally, this role includes taking a role in design, development, regulatory submissions and technical transfer to manufacturing and will produce engineering & CAD support. You will need to be able to communicate ideas, concepts, designs and requirements to a wide range of audiences including surgeons, engineers, sales & marketing, quality and manufacturing.

The Basics:

- Obtain product design requirements from product development and quality and implement them within the product lines.
- Work with all areas to coordinate cross-functional requirements to create, maintain and execute the project plans.
- Execution of the project plan can include generating user needs, design inputs, design development, verification, validation and regulatory submission generation.
- Coordinate preparation and completion of project deliverables: design history file documents, solid models, drawings, and inspection criteria.

What We Need:

The following competencies are required for the position:

- Bachelor's degree in Biomedical, Materials or Mechanical Engineering from a four year college or university.
- Five (5+) or more years industry experience in the medical device, aerospace or other regulated industry involving aspects of design, validation, technical design transfer, quality or manufacturing----preferably all aspects.
- Familiarity with regulatory and quality requirements for implants and how design, development and manufacturing are affected by those requirements.
- Applied understanding of biocompatibility, sterile packaging design, sterilization validations and other final processing requirements.
- Sincere interest in the medical device business with a goal to develop new hip and knee products.
- The ability to adapt to customer, organizational, business, and external influences with integrity, immediate consideration, and action to meet business objectives.
- Flexible and patient attitude towards challenges, such as design and scope changes, helpful to have had experience in a small company or start-up environment.
- Experience drafting, or collaborating on, regulatory submissions for medical devices.
- CAD modeling/drawing creation skills; expertise with SolidWorks Strongly desired.
- Working knowledge of the MPEP and intellectual property laws a plus.

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Who we are:

Start-up? Absolutely. New on the scene? Hardly. Our founders share over 100 years of orthopedic industry experience (but don't feel a day over 35). We make high quality, low cost implants for the global market, and at the end of the day, we give back what we've made. A portion of our profits go to Operation Walk, an organization dedicated to providing free surgical care and medical education to developing countries.

What you'll get:

A competitive salary. Health benefits, retirement, stock options. A flexible work environment. A voice. Each member of our team is a valued contributor working toward a common goal: affordable healthcare, worldwide.

Where we live/work/play:

A temperate valley at the base of the finest mountains the world has to offer. Our office is 20 minutes from seven world-class ski resorts (you can catch another three if you're willing to drive a little farther). We enjoy over 300 days of sunshine to ski, snowboard, hike, climb, bike, golf, fish, boat, and sightsee. Year round.

Apply to:

totaljointortho@gmail.com
or
Total Joint Orthopedics, Inc. 1567 E. Stratford Avenue, Salt Lake City, Utah 84107, (o) 801-486-6070