ACTUATEDMEDICAL®
Innovative motion + Positive outcomes

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Certified...
+ ISO 13485:2016
+ Medical Device Single Audit Program (MDSAP)
+ Women's Business Enterprise (WBE)
+ Women-Owned Small Business (WOSB)

Position Title: **R&D Engineer Level II**
Status: **Exempt**
Reporting Structure: **Director R&D**

Basic Purpose

Actuated Medical is a medical device and technology company focusing in developing, manufacturing and selling products which strive to improve patient quality of life. Many of our products utilize controlled motion and actuated technologies, such as occlusion clearing systems, vibrating needle systems, miniaturized working platforms and MRI-compatible devices.

The **R&D Engineer Level II** relevant experience required is a B.S. in Biomedical Engineering, or equivalent.

This engineer will work in research and development of medical devices, which may result in new designs, processes and/or device optimizations (intellectual property). Product design, development, assembly, testing and data analysis are central responsibilities for the position. Interacting with clinicians, potential industry partners, and vendors is commonplace. Transitioning prototypes to manufacturing level with help from mechanical/manufacturing engineers, while continually assisting in updating the required QA documentation is also a key component of the position.

Essential Duties and Responsibilities

90% R&D Engineer:

+ Design, develop, assemble and test products by utilizing research skills to complete product mechanical and electrical testing, product testing utilizing biological tissues, and initial validation and verification testing, in a team-supported research environment.
+ Assist in analyzing data from product testing and analytical modeling/analysis to utilize in product development.
+ Assist with off-site animal/human clinical research activities (hospitals, clinics, research environments)
+ Assist with on and off-site product demonstrations to clinicians, potential industry partners and potential customers.
+ Develop and support continuous improvement of products and processes within R&D development stages that may result in intellectual property (patents and/or trade secrets)
+ Produce prototypes and components for programs utilizing research and manufacturing equipment, as requested.
+ Ensure that small-scale product assembly procedures and processes are followed, but are continually optimized and are improving toward manufacturing scale production.
+ Purchasing of product and research materials to support R&D efforts, product improvement, and AMI scientific needs. Continually work with vendors.
+ Produce medical device products that meet Product Specifications and comply with Quality Assurance plan.
+ Continually assist in updating all Quality Assurance (QA) documentation for product programs and intellectual property (Design Requirements Documentation, Manufacturing Protocols, etc.).

- Follow AMI notebook policy.
- Follow testing protocol/report writing outlines to aid in device R&D
- You have responsibility and authority to write up and submit to QA, Product Leader and/or Executive Management any employee that does not follow procedures or violates an Actuated Medical Policy(s) including but not limited to AMI's Safety Policy.
- Other tasks that meet the needs to grow AMI.

10% Other duties as assigned:

- Traveling when requested.
- Responsible for work areas. General oversight of R&D area.
- Other tasks that meet the needs to grow AMI.

Education, Requirements and Credentials

- B.S. in Biomedical Engineering or equivalent is required.
- A strong Biomedical Engineering understanding with a focus in Electrical, Mechanical, or Material Science Engineering is encouraged.
- Experience with testing methods, data analysis, problem-solving, and troubleshooting is required.
- Biomedical research experience, especially pre-clinical testing experience is highly preferred.
- High motivation and ability to handle multiple projects is required.
- Strong written and oral communication skills are required.
- Strong ability in prioritizing tasks and following responsibilities to completion is required.
- Knowledge of life/medical sciences, healthcare practices and procedures, as well as an understanding of product design and development methods are highly preferred.
- Proficiency in Computer Software Tools (i.e., Microsoft Office Products) is highly preferred.
- Experience in Design Software (Solidworks), FEA Software (Comsol), and Numerical Analysis Software (Excel, MATLAB, Labview, Scilab, etc.) is encouraged.
- Instrumentation and Data Acquisition (with aided software-based control, i.e., Labview) experience is encouraged.
- Maintain necessary education, requirements, and credentials to interact with vendors and end users both at AMI and in the healthcare setting.

Physician Demands

- Capability of occasionally lifting up to 40 pounds.
- Capable of working in an office environment.
- Capable of working in a manufacturing environment.
- Capable of using proper PPE.

Driving

- Capable of driving a motor vehicle as necessary for company related travel.

Other

+ Be comfortable working in a team-supported research environment.

Exemption
This position is exempt under current applicable laws. See US Department of Labor and Pennsylvania Department of Labor, Fair Labor Standards Act (http://www.dol.gov/compliance/laws/comp-flsa.htm) and Pennsylvania Department of Labor and Industry (http://www.portal.state.pa.us/portal/server.pt/community/minimum_wage_law/10521) for information.

Reviewed and Understood: _____Date:_____

Witnessed: _____Date: _____
Maureen L. Mulvihill