Senior Design Engineer

The Senior Design Engineer will serve as the technical lead for developing complex, electro-mechanical products for the consumer health and medical device markets. This individual is responsible for all aspects of product life cycle management in the area of product development, from inception through engineering design and manufacture and works in concert with Simbex Project Managers to deliver novel product solutions within constraints of budget, schedule, and established quality processes and methodologies. As a Functional Team member at Simbex (Electrical, Mechanical, or Software), the Senior Design Engineer will also be responsible for domain-specific architecture, design, and engineering of products.

ESSENTIAL FUNCTIONS:

- Develops conceptual and detailed designs by analyzing product market requirements and performance requirements
- Performs diverse and complex design, fabrication, modification, and evaluation of mechanical or electromechanical components, subsystems, and systems by applying engineering principles and developing new or unique analysis tools as required
- Determines feasibility of designing new equipment or modifying existing equipment considering technical and economic factors, available resources, time constraints, and company planning by applying advanced analytical methods, creating design solutions, and establishing engineering plans
- Provides technical information affecting long range product engineering planning by researching manufacturing or processing techniques, materials, properties, and process advantages and limitations
- Recommends and implements process control specifications and related documentation.
- Conducts complex analyses and devises tests pertaining to the development of new designs, methods, materials or processes and completes required documentation by applying advanced engineering principles and company standards, and generating detailed reports, procedures, or change proposals
- Develops acceptance, engineering evaluation, development and qualification/certification test plans, procedures, and reports. Compiles and analyzes operation, test, and research data to establish performance standards for newly designed or modified equipment or product
- Investigates pertinent design factors such as human factors and ergonomics, ease of manufacture, availability of materials and equipment, interchangeability, strength-weight efficiency, contractual specification requirements, cost-determining optimum solutions, and implementing recommendations
- Prepares or directs preparation of product or system layout and detailed drawings, assembly drawings, and schematics by coordinating with designers, drafters, or other engineers, interpreting customer and functional requirements, or by using engineering computer-aided design tools and following industry and/or military drawing standards
- Reviews drawings and layouts to ensure clarity, completeness, functionality, and conformity to standards, procedures, and specifications. Identifies design errors, omissions, and other deficiencies, and directs revisions and improvements to engineers or other designers

- Ensures internal project documents are complete, current, and stored according to Simbex's Quality Management System
- Concisely and accurately communicates development progress and results to internal and external customers (both written and verbal)

Additional Responsibilities:

- Direct mentorship and training to staff
- Assist with the development of on-going learning initiatives and staff training activities
- Provide support to Simbex commercialization centers for pediatric medical device (NEPDC; www.nepdc.org) and rehabilitation technology (TREAT; www.treatcenter.org) development
- Assist with preparation of grant submissions
- Minimal travel (on an as needed basis) to participate in off-site meetings (project / training / scientific)

EDUCATION AND EXPERIENCE:

- Bachelors degree (BS) in mechanical, electrical, or a related technical discipline (MS preferred) with 10+ years of medical device and/or combination product development experience
- Demonstrable experience in solving a wide range of difficult problems in imaginative and practical ways, and evaluate alternative solutions that may require coordination across multiple teams
- Thorough knowledge of engineering principles, theories, concepts, techniques, industry practices, regulations (including familiarity with GMP and design control processes as defined by ISO and FDA guidelines), and policies associated with mechanical, electrical, or other engineering disciplines
- Demonstrated ability to lead a diverse cross-disciplinary team of developers across a variety of engineering domains including electrical, software, firmware, mechanical, verification, and validation
- Experience with FDA policies and procedures; demonstrated success with obtaining medical device approval/clearance preferred
- Solidworks CAD proficiency with advanced part modeling and surfacing is strongly desired
- Ideation, industrial design, concept development and sketching experience preferred
- Demonstrable technical competency and experience in mechanical or electro-mechanical systems
- Design for large scale manufacturing experience is strongly desired
- Injection molding / rapid prototyping experience is strongly desired
- Ability to maintain a high level of proficiency while working independently and clearly and concisely communicate as a member of a team
- Familiarity with Agile development and processes preferred
- Strong organizational skills and attention to detail
- Materials Science background or experience is highly desirable
- Structural weldment design experience is highly desirable
- A commitment to our core values of innovation, passion, agility, openness, integrity and social responsibility