1) Title: Senior R&D Engineer

Job Description

- Contributes as a team member on development projects carrying out assigned responsibilities in a timely, diligent, safe, and professional manner. May act as a project leader.
- Conducts user/ergonomic studies with clinical professionals during the product development process in pursuit of user-based product design excellence.
- Supports the organization's intellectual property strategy by documenting data and independent, unique and patentable ideas that results from experimentations and concept generation activities.
- Leads the design and development of new product and product engineering and applies engineering best practices and tools. Provides leadership in design analysis.
- Ensures quality in a product's design for usability, reliability, functionality, marketability, and manufacturability.
- Supports the development of products through knowledge of the clinical and physical performance requirements. This includes all aspects of the product design criteria, product function and customer needs.
- Keeps abreast of latest developments in process technology. This includes molding, automated assembly, packaging, and sterilization. Researches new processes or materials processing technologies for possible new product development.
- Leads product design verification and validation to satisfy product and customer requirement.
- Applies Design to Cost and Design for Manufacturability methods to support project leader in achievement of project objectives.
- Provides technical support to Unit Business(es).
- Contributes to assembly and maintenance the Design History File (DHF).
- Ensures proper design and development documentation as per ISO 13485/FDA QSR Quality System. Creates new SOPs and maintains all relevant SOPs to ensure strict compliance of R&D functional operation with ISO 13485/FDA QSR Quality System.
- Ensures a safe, healthy and environmentally-friendly workplace by observing Company’s procedures and ISO 14001 regulations. Actively involved in prevention, elimination of potential safety hazards and participation in activities which promotes recycling, replacement and reduction of resource materials.
- Follows BD’s Global Product Development System (GPDS).

Job Requirements

- Bachelor/ Masters/ PhD degree in mechanical engineering, biomedical engineering, or related engineering discipline.
- PMP credential, DFSS certification, and/or Six Sigma Green/Black Belt.
• 5 years relevant experience in product design and development with a solid understanding of the product lifecycle.
• Practical and demonstrated experience of solid modeling of parts and assemblies.
• Product design experience in the medical device industry.
• Experience in the design and development of products in accordance with ISO 13485 guidelines.
• Experience in DFSS and applications of first principles in engineering.
• Experience in high volume manufacturing and assembly processes, particularly those of plastic injection molded parts and assemblies.
• Demonstrated hands-on experience with Design Control procedures.
• Experience in a Phase-Gate development process.
• Experience directly applying DOE, statistical methods, and GD&T.
• Experience in designing production equivalent rapid prototypes.
• Complete understanding of technical principles, theories and concepts in the field of product development. General knowledge of related disciplines.
• Proficient in 3D CAD software (SolidWorks preferred).
• Understanding of CAE tools (FEA, CFD, etc.)
• Knowledge of statistical methods and analysis.
• Demonstrated knowledge of applied mechanical engineering in product design and evaluation.
• Strong aptitude for hands-on engineering testing and experimentation in a lab/shop environment.
• Able to identify, break down and solve a variety of difficult technical problems.
• Team player with excellent interpersonal and communication skills.
• Proven ability to work independently with a minimum of supervisor input.
• Disciplined and well-organized in documentation (plans, requirements, drawings, design reviews, and test methods).
• Knowledge of medical device regulations and practices (ISO 13485, FDA QSR, etc.)

Working hours: 7:45am-4:45pm or 9am to 6pm
Company transport provided island wide.

Interested applicants, please submit your applications (include resume) to aprh@bd.com and indicate your reasons for leaving current employment as well as your current and expected salary.
2) Title: Senior R&D Engineer - Systems Engineering

- Responsible for supporting the development of instrument systems used in clinical diagnostics. The systems involved are comprised software, firmware, electronics, hardware, and reagent/consumable components.
- Participate in or lead intra-function teams of engineering, verification, and validation staff to achieve systems design and test goals in addition to participating in or leading cross-functional technical teams to drive and coordinate overall system development.
- Contributes as a team member on development projects carrying out assigned responsibilities in a timely, diligent, safe, and professional manner. May act as a project leader.
- Work with the engineering and scientific staff to develop and execute experimental protocols followed by the analysis and reporting of results.
- Participate in the integration of systems components, including generation of an overall integration plan. Additionally, this individual will support system level engineering verification efforts and support the planning of validation test activities.
- Exercise judgment within broadly defined practices and policies in selecting methods, techniques, and evaluation criteria for obtaining results.
- Use disciplined work methodologies utilizing scientific and statistical methods in resolving problems, devising tests and setting specifications.
- Ensures quality in a product’s design for usability, reliability, functionality, marketability, and manufacturability.
- Supports the development of products through knowledge of the clinical and physical performance requirements. This includes all aspects of the product design criteria, product function and customer needs.
- Keeps abreast of latest developments in process technology. This includes molding, automated assembly, packaging, and sterilization. Researches new processes or materials processing technologies for possible new product development.
- Applies Design to Cost and Design for Manufacturability methods to support project leader in achievement of project objectives.
- Contributes to assembly and maintenance the Design History File (DHF).
- Ensures proper design and development documentation as per ISO 13485/FDA QSR Quality System. Creates new SOPs and maintains all relevant SOPs to ensure strict compliance of R&D functional operation with ISO 13485/FDA QSR Quality System.
- Ensures a safe, healthy and environmentally-friendly workplace by observing Company’s procedures and ISO 14001 regulations. Actively involved in prevention, elimination of potential safety hazards and participation in activities which promotes recycling, replacement and reduction of resource materials.
- Follows BD’s Global Product Development System (GPDS).

Job Requirements
- Bachelor/Masters/PhD degree in systems engineering, biomedical engineering, or related engineering discipline.
- PMP credential, DFSS certification, and/or Six Sigma Green/Black Belt.
- Minimum of 5 years’ experience in developing instrumentation.
- Minimum of 2 years’ experience within a Design Control environment.
- Product design experience in the medical device industry.
- Experience in the design and development of products in accordance with ISO 13485 guidelines.
- Experience in DFSS and applications of first principles in engineering.
- Experience in high volume manufacturing and assembly processes, particularly those of plastic injection molded parts and assemblies.
- Demonstrated hands-on experience with Design Control procedures.
- Experience in a Phase-Gate development process.
- Experience directly applying DOE, statistical methods, and GD&T.
- Experience in designing production equivalent rapid prototypes.
- Knowledge in one or more areas related to diagnostic testing such as signal processing, embedded systems, electronics or software. Knowledge of fluidics, optics, or clinical reagents is also helpful.
- Has experience working on cross functional technical teams and has the capability of providing coordination among groups or functions.
- This person should be experienced with the system development lifecycles and Requirements Development for complex systems.
- Experience in customer, system and subsystem level requirements definition, analysis, management and traceability (preferably with the use of requirements software such as DFSS Cockpit or DOORS).
- Experience in developing architectural and interface designs through interaction with Systems Engineering, Software Engineering, Firmware, and other subsystem domains and teams.
- Proficiency in developing and executing system integration and performance characterization plans and then executing these through virtual simulation and real test scenarios. This includes the creation of tests methods with appropriate scripting languages and tools.
- Experience in systems stress analysis and hazards analysis.
- Demonstrated proficiency leading small teams to achieve technical objectives.
- Experience in Functional Analysis, Interface Management, Maintaining Design Integrity, Scenario Generation
- Experience applying one or more DFSS techniques
- This person should be confident and an active participant in technical discussions and meetings.
- Has exercised independent judgment to determine evaluation criteria for obtaining results.
- Has resolved technical issues in creative and effective ways.

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