



**Position:** Principal Systems Design Engineer

**Department:** Engineering

**Summary:**

This position involves hands-on design engineering, project leadership as a technical-lead-role, and mentorship of junior engineering personnel. The Principal Systems Design Engineer is responsible for leading the design of new products and ensuring that they meet associated requirements. This engineer will be involved in all aspects of the product development life cycle: concept development and feasibility assessment, electronic architecture and design, schematic capture and layout, prototyping, V&V testing, and manufacturing transfer. This position will interface with potential and existing customers to understand product requirements, assist in proposal generation, and ensure customer requirements are satisfied through the design process.

Previous experience in electrical design and testing for Class II and III medical devices under an ISO 13485 quality system is expected. Broad electronics design experience in embedded systems, wireless technologies such as Bluetooth or MICS, power management circuits, sensors, and data acquisition and signal processing is required. Experience in development and integration of firmware is strongly desired.

**Essential Functions:**

Key responsibilities will include, but are not limited to:

- Providing leadership for the definition of the system architecture, the system level requirements for hardware, software, features, accessories, and their flow down requirements to respective subsystems in the forms of:
  - Requirements analysis and decomposition
  - System architecture definition in terms of hierarchical product breakdown structures and interaction/interface mapping
  - Constraints analysis and resolution
- Developing, and managing the development of, requirements and requirements management, including identification of best practices and use of requirement management tools.
- Supporting interaction with cross functional customer facing groups to ensure desired product capabilities are reflected accurately in the architecture description
- Owning Systems Impact Analysis and driving system design options and recommendations for product change requests, scope change requests, and Charter approvals, as appropriate
- Driving, documenting, and delivering high-level system architecture, design, interfaces, risks, and tradeoffs that support product development schedules
- Creating and supporting the creation of system / subsystem architecture design documents (e.g. operational concept, system functionality description, state transition



description, sequence diagrams, systems interface description, interaction diagrams, use cases, verification matrices, etc.).

- Performing Program or Project Tech Lead Role and /or Program Systems Design Lead Role as assigned
- Hands-on electronics design as required: circuit design, PCB layout, system simulation and signal integrity analysis
- Preparing and/or managing the preparation of test plans and the conducting of, or supporting of, Verification and Validation testing utilizing experience testing to IEC 60601, FCC and ETSI standards
- Developing the necessary product documentation including Design History Files, Device Master Records, DFMEA and PFMEA.
- Developing system reliability models and analyze system reliability using reliability theory, statistics and reliability tools e.g. SCRAM
- Acting as a mentor for other engineers

### **Education and Skills**

Bachelor's in Electrical Engineering (BSEE) having 15+ years of relevant work experience with mixed signal circuit design, signal integrity, PCB layout (Altium), prototyping and testing. Advanced knowledge of system engineering principles, including: requirement generation, decomposition and management, system architecture development and management, system design, constraints analysis, risk management, verification, validation, use cases, configuration management, issue tracking. Vast experience developing hardware circuitry design, PCB layout, selection of electronic components, packaging, and system-level build to customer's *Statement of Work* specification. Must have experience with system modeling and simulation using various software tools such as MATLAB/Simulink or similar. Previous experience under ISO 13485 and FDA design controls is required along with experience designing and testing to IEC 60601-1 and IEC 60601-1-2 standards. Must have experience with the entire product lifecycle from conception to production several times over. Shall have launched no less than 5 products throughout career. Can act as systems lead and systems architect throughout the entire product lifecycle. Must have working knowledge of NASA's Systems Engineering Handbook and overall process.

Excellent written and verbal communication skills

Proven ability in problem solving and troubleshooting

Strong attention to detail

Proficiency in using typical bench-top equipment (e.g. oscilloscopes, signal generators, audio analyzers, spectrum analyzers, voltmeters, etc.)

Must be self-motivated and able to work in fast-paced team environment

Ability to work with minimal guidance to make decisions and report progress

Demonstrated leadership role in projects, including ability to provide guidance and direction on the project to less experienced technical personnel

Experience with systems engineering processes, such as requirements management, configuration management, issue tracking tools, etc.

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Proven ability to perform complex engineering analysis and calculations

Strong understanding of ISO 13485, IEC 62304 and FDA quality processes for Class II & III devices

Ability to effectively and efficiently manage time, establish priorities, and direct the work of more junior engineers

Advanced working knowledge of:

1. analog, digital, mixed signal circuits
2. multi-component electrical devices
3. PC interfaces, communication protocols
4. digital design, DSP, wired and wireless communication, signal processing concepts including: block diagrams, filter realizations, Fourier analysis, difference equations and Z-domain analysis
5. software development process, source code control, version control, high and low level programming languages.

For inquiries, contact:

Human Resources

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