Title: Senior Systems Engineer

Chicago, Illinois, United States, Systems Engineering SSA

Description

What does Orthogonal do?

Orthogonal is a software developer for Software as a Medical Device (SaMD). We work with change agents who are responsible for digital transformation at medical device and diagnostics manufacturers. These leaders and pioneers need to accelerate their pipeline of product innovation to modernize patient care and gain competitive advantage.

Orthogonal applies deep experience in SaMD and the power of fast feedback loops to rapidly develop, successfully launch, and continuously improve connected, compliant products—and we collaborate with our clients to build their own rapid SAMD development engines. Over the last eight years, we've helped a wide variety of firms develop and bring their regulated/connected devices to market.

Who are we looking for?

The Senior Systems Engineer will be working with the product, platform, and software engineering team to provide design control and software/systems development guidance.

As a Senior Systems Engineer, you'll apply cutting-edge techniques and technologies, build great products, develop reusable platforms and grow great teams.

You'll be a key technology and process leader at Orthogonal and intimately involved in almost every aspect of a solution lifecycle from project inception, engineering design, implementation to maintenance and continuous improvement.

These solutions include cloud-based applications, mobile, web, and web services for the life science industry, and are used to manage, process, and store patient health and medical device data to be used for patient diagnosis and treatment.

We are looking for someone who thrives in a start-up environment and demonstrates:

- Intensely collaborative
- Passionately focused on the customer
- Detail oriented
- Disciplined executor of responsibilities
- Tenacious commitment to continuous improvement
- Relentless drive to win
- Intense curiosity on technology
- Flexibility and willingness to learn

You're comfortable in a client facing role, being a technology leader as well as a team leader and mentor to junior members of your team.

What will you do at Orthogonal?

- Active participation in design, development, and deployment activities, working closely with Architects, Engineers, Product Managers, Scrum Masters, and Program Managers.
- Curate traits of quality in the culture of software medical device development at Orthogonal.
- Contribute to translating and articulating user or stakeholder needs into an engineering requirement.
- Define the inputs and outputs needed to make the sub-systems work independently and then the system level inputs and outputs needed to make the system work when fully integrated.
- Authoring software product design specifications documentation such as user stories, acceptance criteria and FURPS+ matrices
- Lead Risk Management, Design Assurance, Design Verification, Design Reviews, and Reliability Planning activities.
- Develop high level processes and efficiency improvement and analysis tools
- Develop, manage, and maintain design history files and related deliverables.
- Manage and logically organize data to identify and describe problems and assess the suitability and quality of technical solutions.
- Maintain up-to-date knowledge of medical devices, technologies, and regulatory landscape related to the company's products.
- Perform complaint, failure, and risk management activities, develop mitigation and risk control strategies, and generate supporting documentation.

- Support product sustaining activities including value engineering, reliability improvements, manufacturability improvements, field issues with technical and impact analysis.
- Ensure that documented test procedures are replicable and follow FDA, EU MDR, HIPAA regulations and guidance, as well as ISO 13485, ISO 14971 and IEC 62304 standards.

What kind of educational and technical background will you need?

- BS or MS in Bioengineering, Biomedical Engineering, Computer Science or a closely related field.
- 6 years of experience in doing similar kinds of Quality or Systems Engineering related work.
- 6+ years of hands-on software development experience.
- 6+ years of experience in software medical device development classified as Class 2 and/or Class 3 medical device or similar kind of work
- Demonstrated applied expertise in EU Medical Device Directives and FDA design control requirements (21 CFR 820.30) as applied to medical device software and medical device regulations including ISO 13485, ISO 14971, and IEC 62304.
- Demonstrated applied expertise in writing different design control deliverables for Class 2 and/or Class 3 medical device software.
- Familiarity with SaMD/software-only medical device development
- Familiarity with health and data privacy regulations.
- Familiarity with the role of Human Factors/Usability in the software development lifecycle.
- Understanding of the Principles of Cybersecurity and Privacy Practices, Procedures and Regulatory Frameworks surrounding Medical Device Software embodied in FDA Guidance, NIST Guidance, ISO 27001, UL-2900-1.
- Experience as a quality engineer in the adaptation of medical devices to new regulatory regions would be a plus.
- Experience or training in the area of software testing such as manual testing, building automated tests, smoke testing, black box testing, regression testing, system testing, integration testing, etc., is required.
- Strong ability to work with internal technical team, eliciting and supporting customer requirements and delivering product per requirements as well as a strong ability to efficiently manage multiple projects at the same time is required.

- Experience or willingness to work in a multi-skilled environment (possess cross-disciplinary skills or ability to grasp requisite skills outside of core skill set).
- Ability to make independent decisions and have a successful track record of influencing key stakeholders.
- Strong interpersonal and communications skills – Must be confident and capable in a customer facing role.
- Demonstrate proactive and strategic thinking
- Strong oral and written skills

BENEFITS

What will you learn, and how will you grow?

You'll be at the center of digital health and the new way of developing medical software. You'll develop a deep understanding of the connected care landscape within the regulatory environment, including wearable sensors, wireless connectivity, mobile technologies, AI algorithms and cloud computing. You'll be able to apply cutting-edge techniques and technologies, build great products and great teams.

This position offers a competitive salary, great benefits and an opportunity to develop new skills and help establish new standards in the burgeoning world of medical devices and in the design and development of Software as a Medical Device (SaMD), digital therapeutics (DTx), and other types of connected medical devices.

Interested? Send inquiries to careers@orthogonal.io