JOB DESCRIPTION

POSITION TITLE: *Software Technical Writer*

REPORTS TO: *Software Development Manager*

EXEMPT/NON-EXEMPT: Exempt

JOB SUMMARY:

The Software Technical Writer interfaces with users, system owners, and software development staff to understand the intent, function, and implementation of software and translate these into clear and concise, written documents. In the context of the software development lifecycle (SDLC) process, epics, user stories, requirements, tasks, and tests all documented within the SDLC tool in order to manage the work performed by the developers and testers. Detailed technical specifications including user interface design, code implementation, database implementation, asynchronous services, architecture diagrams, flow charts, etc. are written to prevent knowledge loss in the event of software team turnover, speed the onboarding of new team members, allow for faster troubleshooting of issues, and reduce the number of development/testing iterations. The Software Technical Writer authors user documentation such as manuals, release notes, and help content for training and reference purposes for both internal and external users. Additionally, for FDA regulated applications (i.e., software as a medical device and computerized systems used in the conduct of clinical trials), the Software Technical Writer is responsible for creating, adapting, and associating software documentation to satisfy regulatory design control and validation requirements, using MMI's electronic Quality Management System (eQMS) platform, procedures, and forms. Such regulatory documentation includes definition of user needs, design inputs, design outputs, design verifications, design validations, risk analysis, and traceability.

DUTIES AND RESPONSIBILITIES:

- Participate in software design discussions and interviews with end users, system owners, and software development team members
- Familiarize with intended use and functionality of existing software that is proprietary to MMI or that is planned to be purchased/licensed for use in a regulated context
- Develop training materials, manuals, help content, and release notes for internal and external users
- Document epics, user stories, software requirements, and design specifications for use in the SDLC process and for future reference
- Translate and associate internal software documentation to meet FDA regulatory design control and validation requirements within MMI's eQMS platform and associated forms

- Author and execute software test scripts to verify that installation, operational, and performance requirements are met
- Understand Medical Metrics Quality Policy and support the achievement of the organization's quality objectives and take corrective action when necessary to mitigate organizational risk
- Comply with company policies and procedures, as well as ISO 9001 and Current Good Clinical Practices (cGCP's) relative to job tasks
- Ensures compliance with HR policies and procedures

EDUCATION AND EXPERIENCE:

- Bachelor's degree in English, communications, computer science, or similar discipline
- Minimum of 3 years technical writing / business analyst experience as part of a software team
- Professional experience with FDA regulatory validation of computerized systems is preferred

SKILLS REQUIRED:

- Exceptional technical writing ability in English with careful attention to detail and completeness
- Well versed in multiple SDLC and knowledge base tools and processes
- Aptitude for mastering new software packages and appreciating design considerations
- Ability to quickly grasp and concisely convey technical concepts to a general audience
- Highly self-motivated and committed to exceeding planned objectives
- Experience implementing ISO 13485 and 21 CFR Part 820 is strongly preferred

COMPANY & COMPENSATION:

- Medical Metrics Inc. (MMI) is a fast-growing, independent imaging core laboratory and medical imaging solutions company based in Houston, TX. MMI provides image analysis and consulting services to medical device, biologics, and pharmaceutical companies in support of their clinical trials and product R&D.
- Competitive salary, commensurate with experience and qualifications
- Excellent benefits package including medical, dental, and life insurance, 401(k) plan, and paid vacation and holidays

For further information, please contact:

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OR

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