

Software Remodeling, Inc. Improves Medical Device Software Development With RequisitePro

Software Remodeling, Inc. (SRI) provides system analysis, software development and system integration services for diverse industries. Specializing in real-time, embedded, mission-critical systems, SRI has years of experience in developing software for medical devices.

One of the company's current projects is the development of the software, electronic and mechanical subsystems for a state-of-the-art infusion pump. An infusion pump delivers fluids to a patient intravenously.

Approximately 40 to 50 people from different organizations across the U.S. are working on the development project, including marketing, product engineering, electronic and mechanical engineering, and testing staff members.

Because of SRI's commitment to high-quality software project management, team leaders implemented RequisitePro, Rational Software's requirements management tool, to improve the definition, management and communication of project requirements throughout the development lifecycle.

RequisitePro Helps SRI Developers Satisfy Customer Requirements

"One of the main benefits we have received from implementing RequisitePro is the ability to trace requirements from the highest-level specifications through software design documents and individual test

plans," said Cecelia Rogers, SRI's Senior Software Engineer. "This traceability not only ensures that customer needs are met but also keeps us from implementing 'rogue' (extra or unnecessary) requirements."

Ms. Rogers is responsible for the definition of software requirements and the development of the Software Requirements Specification (SRS). The SRS is a critical document to the project because it describes exactly what the device needs to do to meet customer and safety requirements. In medical development environments, it also becomes part of the 510(k) submission to the FDA.

The 510(k) submission includes all of the project documentation required to show that requirements and potential hazards have been traced and tested. Typically, this documentation (referred to as the "documentation tree") includes the customer functional specification, hazard analysis, software requirements specification, software design document, requirements and architecture documents, testing plans and procedures, and test results.

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RequisitePro Supports SRI's Conformance To Industry Standards

Prior to their current positions at SRI, SRI managers were involved in defense-related software development. Consequently, SRI's current project management processes follow the 2167A military standard. This standard sets guidelines for both project documentation and deliverables, such as the software requirements specification and the software design document.

As a medical device developer, SRI must also satisfy FDA and GMP guidelines and standard operating procedures. Safety-critical requirements must be reviewed with extra scrutiny to ensure the code is accurate and the system is thoroughly tested.

Testing the potential hazards of every device subsystem—either software, electronic or mechanical—is extremely important for medical devices. For every potential failure mode, team members must perform a hazard analysis. In other words, they must answer the question, “If X fails, how will the system react?”

SRI utilized RequisitePro to answer this question by tracing all requirements that need to be tested and specifying how each requirement will be tested (i.e., by analysis or demonstration). Developers and testers can simply print out the hazard analysis and testing matrices for selected requirements and their attributes and include it with the 501(k) submission.

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RequisitePro Saves SRI Time and Resources

Prior to implementing RequisitePro, requirements were either managed manually or with an in-house, proprietary system. Developers would have to export requirements data from Microsoft Word in a text file and import them into a relational database. This process was extremely time consuming and labor intensive. Requirement changes could not be traced or communicated effectively.

“RequisitePro has greatly improved our project management process. The tool helps us manage document releases and reports quickly and easily. What used to be a one- to two-hour job of manual processing is now a five-minute job with the click of a mouse. In addition, RequisitePro assists us in making sure that all requirements are well-written, unambiguous and testable,” said Jeff Rogers of SRI.

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SRI Improves Team-Based Communication With RequisitePro

Because RequisitePro allows users to custom-design fields and attributes within its requirements repository, SRI has created its own assignment field. Team leaders use this custom field to communicate responsibility for specific requirements to other members of the team, both inside and outside the SRI organization.

“I can assign requirements to external project team members without having to generate a separate memo or e-mail. The assignment field tells people in real-time what they should be working on,” said Ms. Rogers.

“When changes are made to the project documents or the requirements database, RequisitePro matrices bring attention to any conflicts. These flags have become a communication tool for us and have made us more productive,” she explained.

Jeff Rogers added, “RequisitePro helps our team immediately resolve any conflicts that appear. When a requirement

in the customer functional specification changes, our team uses RequisitePro’s traceability feature to immediately identify the ‘suspect links.’ By printing a suspect link report, we can determine what change requests need to be made and what tests have to be performed.”

RequisitePro Works In Conjunction With Other Tools

SRI uses RequisitePro in conjunction with PVCS Version Manager and PVCS Tracker for effective version control and change management. Users are required to “check in” and “check out” of RequisitePro to ensure changes are managed and documented throughout development. All changes are implemented within a structured change request process and approved by an internal Change Control Board.

SRI’s Development Environment

- Needed automated tool for managing, tracing and communicating requirements
- Cross-functional development team required immediate information on requirement changes
- Highly-regulated medical device development environment

RequisitePro Solutions For SRI

- Improved requirements definition, control and change management
- Traceability helps determine impact of requirement changes on software design and testing
- Requirements, attributes and documents are shared with team members across departments
- Supports efforts to conform to industry standards

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AR509: rev 9/98. Subject to change without notice.