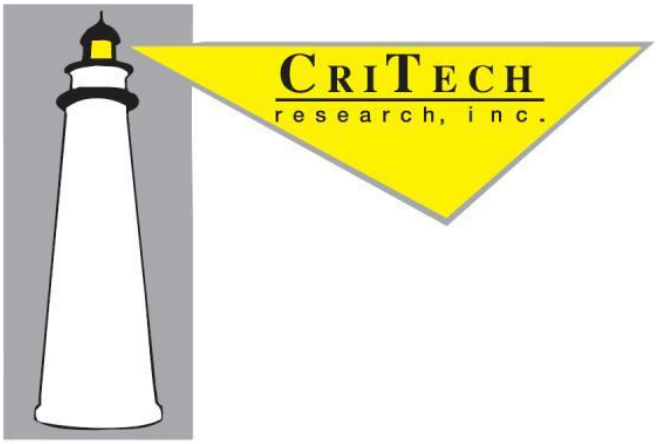

THE IMPORTANCE OF
INDEPENDENT VERIFICATION AND VALIDATION
OF SOFTWARE IN THE MEDICAL DEVICE INDUSTRY

AN OPPORTUNITY TO REDUCE COSTS AND MITIGATE RISK

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Abstract

In today's highly competitive market, many medical device companies opt to take an approach to Verification and Validation (V&V) that minimizes an independent and objective assessment. The reason for taking this minimalist approach is often because it's perceived by some executive teams as costing less than a rigorous approach offered by a third party. In fact, the opposite is true. Return on Investment (ROI) studies show that **ROI for IV&V can conservatively be 85% above the cost** associated with the IV&V.[1] Much of the ROI comes from early detection of errors, a result of the synergistic, parallel efforts of development and testing.

Introduction

The benefits of Independent Verification and Validation (IV&V) of medical device software are many. The purpose of this paper is to discuss the value of Independent Verification and Validation and how it can **reduce costs, mitigate risk, and provide better products.**

The FDA's Guidance states: "Validation activities should be conducted using the basic quality assurance precept of 'independence of review.' Self-validation is extremely difficult. When possible, an independent evaluation is always better, especially for higher risk applications."[2]

IV&V also identifies software design failure, which is one of the most common causes of medical device recalls per the FDA's Medical Device Recall Report FY2003 to FY2012.[3]

Background: What is Software IV&V?

V&V is defined as Verification and Validation. **The "I" part in IV&V is for Independent**. In the field of software engineering, V&V takes a rigorous approach in determining if a product is built correctly and if the correct product is built.

- Verification:Is the product built correctly?
- Validation: Is the correct product built?

The IEEE Standard for Software Verification and Validation states that classical IV&V is generally required for the development of software systems found "critical" in nature (i.e., those which can result in loss of life, loss of mission or significant social or financial loss) through regulations and standards imposed on the system development.[4]

Independent V&V is necessary to establish technical, managerial and financial independence.[5] The following is taken directly from the IEEE Standard for Software Verification and Validation.

Technical Independence

Technical independence requires the V&V effort to utilize personnel who are not involved in the development of the software. The IV&V effort must formulate its own understanding of the problem and how the proposed system is solving the problem. Technical independence ("fresh viewpoint") is an important method to detect subtle errors overlooked by those too close to the solution.

Managerial Independence

Managerial independence requires that the responsibility for the IV&V effort be vested in an organization separate from the development and program management organizations. Managerial independence also means that the IV&V effort independently selects the segments of the software and system to analyze and test, chooses the IV&V techniques, defines the schedule of IV&V activities, and selects the specific technical issues and problems to act upon. The Software IV&V effort must be allowed to submit to program management the IV&V results, anomalies, and findings without any restrictions (e.g., without requiring prior approval from the development group) or adverse pressures, direct or indirect, from the development group.

Financial Independence

Financial independence requires that control of the Software IV&V budget be vested in an organization independent of the development organization. This independence prevents situations where the Software IV&V effort cannot complete its analysis or test or deliver timely results because funds have been diverted or adverse financial pressures or influences have been exerted.

The extent to which each of the three independence parameters (technical, managerial, and financial) is vested in a V&V organization determines the degree of independence achieved.

The Opportunity

Significant additional savings can be associated with risk mitigation. What is the cost of your company missing a product launch date? What is the cost of a recall? Is it $1M, $50M, or more? **Can your company afford to miss a market window of opportunity?**

The escalating role of software in the medical device industry intensifies the importance of Software IV&V.

Even as the medical device industry becomes more competitive and driven by more aggressive time-to-market deadlines, device manufacturers need to provide safety assurances for software being developed. Software-related errors in medical devices

have caused serious injury and even death, so the importance of verifying and validating the software is safe, reliable, and secure is critical.

An independent party is more likely to approach the V&V process with a mindset to "break the system" thereby identifying any software defects and functions that could result in hazardous situations leading to harm – **mitigating risk**.

There needs to be a proportionate budget allocation for time, money and resources to sufficiently test, document and trace the system.

The Benefits

Implementing all three forms of independence as part of the Software IV&V effort offers many benefits.

These include:

Quality and Process Improvement

Software IV&V provides checklists, templates, and other tools to improve the quality through a more controlled software development process. Software IV&V promotes an objective engineering analysis enabling improved detection of errors that may be missed by someone intimate with the development.

Early Detection of Design Errors

Significant cost reduction can be realized when improvements are implemented and errors remediated at the earliest point, before consequences become major. This begins with identifying defects and ambiguous statements in the requirements.

Additional benefits can be realized through this early detection by reducing the potential for failure in the field, which could have significant impact on patient health and the company's finances and reputation.

Lower Management Time Commitment

Better process provides management with improved and objective visibility into the progress and quality of the effort. Utilizing proven tools, techniques, and processes, Software IV&V can reveal risks, mitigation strategies, and opportunities for improving efficiency and effectiveness, reducing the burden on management.

Reduced Overall Cost

By committing to Software IV&V, the removal of the external pressures can assure the right product was built and the product was built right, reducing the potential for delay, negative events in the field, and low market acceptance.

Significant cost reduction can be realized when improvements are implemented and errors remediated at the earliest point before consequences become major.

Improved process and quality have the potential for future savings on next generation devices or other product extension opportunities.

Benefits Conclusion

Software V&V is a required component of the software development process in the regulated Medical Device market. Software **Independent** V&V is the preferred method, especially for higher risk applications.

Important benefits are realized through Software IV&V. Benefits include significant risk reduction from early error detection, improved process throughout the life cycle, and complete/compliant documentation. This approach can produce a quality product that will be compliant with appropriate regulatory standards, on time, and within budget. IV&V has been shown to reduce costs and mitigate risk.

Call to Action

Significant additional savings can be associated with risk mitigation. What is the cost of your company missing a product launch date? What is the cost of a recall? Is it $1M, $50M, or more? **Can your company afford to miss a market window of opportunity?**

As a medical device company CEO, company CXO, Program Manager, or Engineering Manager, you're already aware of your fiduciary duty.

Please consider the questions listed below. If you answer yes to any of them, please contact CriTech today at 734-668-0005 and mention White Paper response.

- **Does your company currently have cost saving initiatives associated with software development?**
- **Does your company currently have initiatives associated with risk mitigation?**
- **Does your software process currently lack true IV&V?**

About CriTech Research

CriTech has over 23 years of experience providing efficient and cost-effective solutions, tailored to meet customer specific needs. We have worked on more than 400 projects and have an exceptional track record – 100% of our submissions have received FDA or EU approval!

CriTech makes sure your medical device uses rigorously tested, fully compliant software. CriTech provides software engineering services for safety-critical software and systems. Our customers range from large, established companies to startups, with products from all FDA device classes (I, II, III) and IEC 62304 software safety classifications (A, B, C).

CriTech is an objective, independent third-party who's determined to make sure your software is safe and who are experts in medical device software verification and validation. In addition to software IV&V, CriTech provides software safety engineering, software remediation, and software development. A detailed list of services is provided on CriTech's website at www.critech.com.

About Bob Rajewski

Bob Rajewski is Co-Founder and President of CriTech Research and is a recognized industry expert in the field of medical device software engineering. He has been involved in the medical device business for over 23 years and has served as an instructor for AAMI/FDA courses on software regulations and software verification and validation.

Notes

1. Authors: Dr. James R. Eckardt, Timothy L. Davis, Richard A. Stern, Dr. Cindy S. Wong, Richard K. Marymee, and Arde L. Bedjanian, "The Path to Software Cost Control," *Defense Acquisition University | Defense ARJ and Defense AT&L Publications,* (Nov-Dec 2014 Issue), accessed March 15, 2017. http://dau.dodlive.mil/2014/12/19/the-path-to-software-cost-control/ Note: In 2012, GreenDart, along with the NASA IV&V Facility in West Virginia, conducted a study into the long term effects of IV&V on program development costs. Based upon the NASA-provided development and IV&V defect-identification information for 31 programs, the paper concluded the ROI for IV&V ranged from a conservative 85 percent to a maximum 294 percent above the cost of performing the IV&V.

2. "FDA General Principles of Software Validation," Section 4.9 Independence of Review, Food and Drug Administration, document issued January 11,2002, p. 12, accessed on March 15, 2017. https://www.fda.gov/downloads/ medicaldevices/ deviceregulationandguidance/ guidancedocuments/ucm085371.pdf

3. "FDA Medical Device Recall Report FY2003 to FY2012." FDA Center for Devices and Radiological Health Office of Compliance, Division of Analysis and Program Operations, accessed March 15, 2017. www.fda.gov/downloads/AboutFDA/CentersOffices/ OfficeofMedicalProductsandTobacco/ CDRH/CDRHTransparency/UCM388442.pdf

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5. "IEEE Std 1012-1998 IEEE Standards for Software Verification and Validation," 57.

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