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C-Scrum: Agile and Automated Software Development for Digital Health

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Abstract. Digital health software requires stringent certification, demanding plan-driven development that seemingly contradicts Scrum's agile adaptability. We introduce C-Scrum (Compliant-Scrum), a hybrid model bridging this gap. C-Scrum incorporates feature-based risk analysis, automated compliance tracking, and CI/CD integration. Expert evaluation confirmed C-Scrum's intuitive design and viability for maintaining both compliance and agility.

Keywords. IEC 62304. digital health. medical software development. SaMD.

1. Introduction

The growing digital health market faces challenges developing compliant Software as a Medical Device (SaMD), particularly adhering to IEC 62304:2006/AMD 1:2015 [1]. IEC 62304 and normative references are essential for quality and emphasize plan-driven processes, that contrast with agile's iterative, deliverable-focused nature. This paper adds to the bridging of approaches discussed by Gallina et al. [2]. C-Scrum is a hybrid model designed to merge IEC 62304 requirements into an agile development.

2. Methods

C-Scrum was developed using design science research. The model is evaluated against 152 regulatory requirements extracted from the IEC 62304. It combines plan-driven regulation with agile principles, minimizing developer compliance overhead while automating compliance tracking and artifact generation where possible. A pilot evaluation was conducted with internal workshops explaining and using the developed process (12 participants) and two expert interviews (10+ years experience).

3. Results

C-Scrum extends Scrum with compliance activities while maintaining agility. Development cycles begin with stakeholder requirements, followed by risk analysis and

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safety classification. In a representative scenario depicted in Figure 1, a nutrition tracking feature is first classified as safety class A, before undergoing development sprints incorporating requirements analysis, architectural design, implementation, testing, and compliance tracking. The Compliance Tracking Table (CTT) manages feature compliance state. C-Scrum leverages a CI/CD pipeline to automate static/dynamic tests (e.g., ESLint, Jasmine/Karma), artifact generation, requirements traceability, and compliance feedback. Feature-dependent risk analysis allows individualized safety classifications, optimizing efficiency by focusing on compliance activities during sprints.

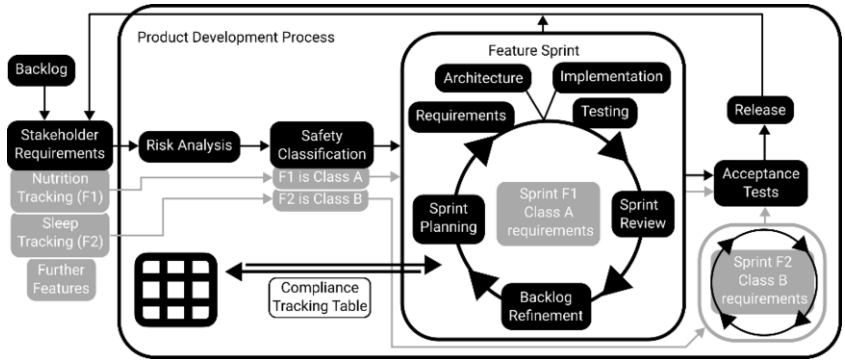

Figure 1. C-Scrum development cycle with two features.

4. Discussion

C-Scrum effectively integrates agile methodologies and IEC 62304 covering 92 of 152 extracted requirements with partial automation possible for 31 requirements. Feature-based risk analysis and flexible activity management through a CTT enable responsiveness to evolving needs. CI/CD pipeline automation generates artifacts, maintains traceability, and provides feedback, minimizing developer overhead. The intuitive design of C-Scrum and the CTT was confirmed by developer and expert feedback. However, C-Scrum requires further validation. Future work will expand the evaluation, gathering quantitative metrics (development velocity, defect rates, audit outcomes) from diverse organizations to comprehensively assess C-Scrum's impact.

5. Conclusions

C-Scrum offers a practical and efficient methodology for developing compliant SaMD while retaining the core advantages of agile. It streamlines compliance and automates key processes, enabling the creation of high-quality, regulatory-compliant software.

References

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