

Lean/Agile Software Development Methodologies In Regulated Environments – State of the art

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Abstract. Choosing the appropriate software development methodology is something which continues to occupy the minds of many IT professionals. The introduction of “Agile” development methodologies such as XP and SCRUM held the promise of improved software quality and reduced delivery times. Combined with a Lean philosophy, there would seem to be potential for much benefit. While evidence does exist to support many of the Lean/Agile claims, we look here at how such methodologies are being adopted in the rigorous environment of safety-critical embedded software development due to its high regulation. Drawing on the results of a systematic literature review we find that evidence is sparse for Lean/Agile adoption in these domains. However, where it has been trialled, “out-of-the-box” Agile practices do not seem to fully suit these environments but rather tailored Agile versions combined with more plan-based practices seem to be making inroads.

Keywords: Software Development, Regulated Environment, Lean, Agile, Medical Device, Embedded-Software, Safety-critical

1 Introduction

In this report we investigate the contemporary practices of Lean/Agile Software Development methodologies, as practiced in the regulated safety-critical domains. Of particular interest to us is how applicable these methodologies are within the domain of medical device software development, and whether the benefits that have been reaped from *Lean manufacturing* [1] can be achieved in this specific domain. We aim to identify areas which require further investigation and which will assist companies in understanding and adopting such beneficial software development practices.

1.1 Lean and Agile Software Development

Lean Software Development can be viewed as the application of the concepts and principles, which drive Lean Manufacturing [1] and [2], to the practice of developing software. Robert Charette - the originator of Lean Development - sees it as a key

component in building a change tolerant business [3]. The key difference he says between Lean and Agile is that Agile is a bottom up approach while Lean is a top down approach. He developed the 12 principles of Lean Development [3] which have very close similarities with the Agile manifesto, and so we see this as the point where Lean concepts meet Agile software development practices. By applying the specific Lean principles [2] within the context of the software development domain, we can see how many of the Agile software development techniques support them [4],[5] and [6].

As a result the boundary between Lean Software Development and Agile Software Development is something that is currently being debated. We view Agile methods as supportive practices of a Lean software development philosophy, and so for the purpose of this report we treat them as one while bearing the distinction in mind.

1.2 Regulation

The increasing complexity of electronic devices is making the hardware and software development processes much more interlinked and so any software development methodology used must take that into consideration. These hardware-software systems are playing an increasing role in our everyday lives, and the obvious safety element is of paramount concern. Various standards have been introduced to help ensure the highest level of confidence in the safe functioning of such systems, and while the regulatory standards are quite rigorous, they are not necessarily prescriptive. Standards, such as the RTCA's¹ DO-178B standard [7] for the aviation industry, and ISO 13485:2003 [8] for medical devices, do not impose any particular software development methodology. The important thing is that the processes, activities and tasks, as identified by the regulations, are being implemented.

2 Analysis of the Literature

The information presented here is mostly drawn from the results of a Systematic Literature Review (SLR)² into the practices of Lean/Agile development in the medical device industry. The SLR was carried out following the guidelines by [9] and quickly showed there to be a lack of published material in this specific area. In order to progress our investigation we widened our review to cover regulated safety-critical embedded-software development in general.

The Agile methodologies most reported throughout the literature were XP and SCRUM (Fig. 1), but one of the areas we were interested in investigating was the 'flavour' of Agile being adopted/trialled in these domains (Fig. 2). From the data there are clear indicators in support of a combination of Agile and more traditional planned-type (Agile-Planned) software development practices.

¹ Radio Technical Commission for Aeronautics (www.rtca.org)

² <http://staff.lero.ie/ocawley/Publications/Lean-Agile-in-medical-devices/>

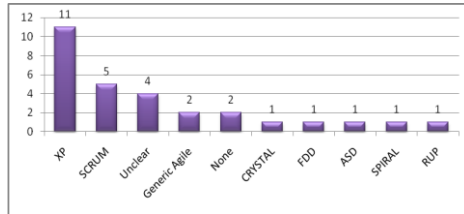


Fig. 1. Methodologies reported
(Y-Axis shows the number of publications)

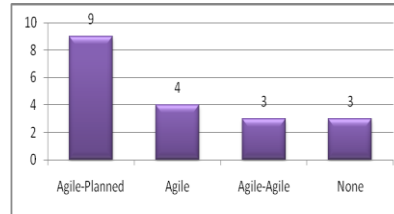


Fig. 2. Agile 'Flavour' being reported

2.1 State of methodology adoption

There are many reports supportive of the use of Lean/Agile methodologies in embedded-software development, including regulated environments such as medical devices. Within the Aerospace industry for example, [10] found that nearly all Agile practices can be mapped to the DO-178B [7] regulatory standard and yet the Aerospace industry has been slow in adopting them. Similar mappings were performed [11] [12], finding that while most of the DO-178B requirements can be mapped to XP, SCRUM, CRYSTAL practices, some are outside the scope of these methodologies and some need to be re-interpreted. [11] found that, similar to other embedded-software domains, the further on in the life-cycle you are, the less agility it is possible to maintain. The final stage of certification is where they see the least amount of agility possible. Interestingly, the Open-DO Initiative³ is calling for a more lean and open-source approach to aviation software development. They state that: *“By leveraging on lean approaches and agility we aim... to shift the focus of safety-critical software development to more continuous and incremental certification approaches.”*

Specifically in relation to the medical device industry, our industry involvement within a medical device manufacturing plant is demonstrating that interest is being expressed in a more lean approach. This is not surprising since the development lifecycle of a medical device is typically measured in years, and so any mechanism that will help reduce this, and thereby provide a competitive edge, is worth investigating. The literature has reports of successful Agile implementations but, as with the embedded-software domain in general, there are caveats which have led to ‘flavours’ of Agile methods being implemented. [13] took a cautious approach at first followed by a full SCRUM implementation. [14], developing software for a specific medical device, note the most important thing for Food and Drugs Administration (FDA) approval is the need to perform formal review and approval steps. They implemented a hybrid Planned-Agile methodology in order to get the benefits of agility while maintaining discipline around certain areas such as documentation. [15] implemented Agile (XP and Scrum) in Medtronic, a company developing class III medical device⁴ software. They found that the practices of pair-programming and test-driven development provided early feedback and better quality. [16] discuss the

³ <http://www.open-do.org/about/>

⁴High risk devices whose failure or misuse would likely cause serious patient injury (EU council directive 93/42/EEC)

successful implementation of Agile practices within Abbott's diagnostic division, and concluded that: "...an agile approach is the approach best suited to development of FDA-regulated medical devices". A strong endorsement indeed. [17] made use of a combination of XP, Scrum and Organisational Patterns to overcome system constraints and regulatory issues related to safety.

Deciding how to begin adopting Agile development in this context is another source of uncertainty. [18] developed a comparative process selection model, while more recently [19] proposed six recommendations when considering Agile adoption in embedded systems development. Specifically related to mission and life-critical systems, [20] developed a three-stage process to help determine the applicability of agile practices to a company's specific environments.

2.2 Some Issues Encountered

As we might expect in a regulated environment, there is a burden of proof which must be met in demonstrating compliance. The validation and verification steps are obvious areas which are focused on. [21] suggests that XP's focus on automating testing can benefit critical systems, but suggests that it should be tried and evolved further to meet the specific needs. To facilitate the requirements of safety demonstrations throughout the lifecycle, [22] developed a formal specification language for nuclear engineering applications. [23] reduced the testing effort in Guidant by between 25% and 90% by means of a Pattern-Oriented Scenario-Based testing approach which supports a Lean/Agile process.

Similarly, issues with refactoring are highlighted, such as the potential to invalidate earlier certification (credit) [12], or to introduce timing issues [24]. A workable configuration management system combined with relentless testing can help.

From a regulation point of view, it is imperative that there is full traceability right throughout the development lifecycle. [25] suggests that the Agile practice of single sourcing information greatly simplifies requirements traceability within regulated development. [6, 25] point to source control management (SCM) as being a fundamental best practice which assists traceability, while [26] propose building upon the practice of TDD to produce a requirements traceability matrix as a direct by-product of the TDD process.

Any Lean or Agile strategy can only succeed if the people involved are organised and motivated appropriately. [27] identified a collection of practices for Lean governance of software development projects. [25] says that in his experience there are quality-oriented Agile development practises which are much better suited to regulated environments than traditional practices. Management training [28], "Making Allies and Friends" [15] are ways used to help in the transformation. If the right attitudes and management supports are not in place, the effort may be doomed from the start [29].

3 Conclusions and Further Work

We found only a small number of publications which could indicate a very low-level of adoption of Lean/Agile methods in regulated, safety-critical domains, however, it may simply indicate a reluctance of companies in these domains to make their internal

practices public. A noticeable lack of reference to the concept of “Lean Software Development” (LSD) was evident. We feel however that due to its relatively recent growth in popularity, LSD has not had time to be adequately defined, evaluated and trialled. The potential of LSD for safety-critical regulated domains needs further detailed investigation.

Starting down the Lean/Agile road can be difficult. We believe it would be very useful to look at developing a roadmap for such companies to trial specific Lean/Agile practices within the constraints of their environments while minimising the risk to compliance.

While much focus is given to the more physical practices, very little is said about what corporate operating procedures are needed to be in place [30]. It would be useful to look at the governance of Lean/Agile software development in these domains with a view to identifying how to design policies and product lifecycles which support the software development teams in a Lean/Agile manner.

Finally, we noticed very little reference to the issues associated with Global Software Development (GSD). We feel that while GSD is currently well researched, it would be worthwhile to examine GSD issues within the safety-critical regulated industry.

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