Chapter 39
Adapting Agile Practices During the Evolution of a Healthcare Software Product

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ABSTRACT

Agile Software Development (ASD) can be considered the mainstream development method of choice worldwide. ASD are used due to features such as easy management and embrace of changes, where change in requirements should be taken as a positive feature. However, some domain verticals, such as medical-healthcare, are classified as critical-safety system, which usually requires traditional methods. This chapter presents a practical use case describing the evolution of a software product that was conceived as a wellness software for end-users in mobile platforms to a medical-healthcare product restricted to regulatory standard recommendations. It presents the challenges and how the ASD is compatible to standards such as ISO/IEC 82304-1.

INTRODUCTION

Agile methods can be considered one of the most adopted methodologies for software development nowadays. When considering the development of consumer-based services and applications, which are mostly focused for end-users in mobile and cloud platforms, Agile Software Development (ASD) is the

DOI: 10.4018/978-1-6684-3702-5.ch039

de-facto methodology. ASD are used due features such easily management and embrace of changes, where change in requirements should be taken as a positive feature. However, some domain verticals, such as medical-healthcare, are classified as critical-safety system, which usually requires traditional methods where requirements are well stablished before development, and validation and verification are usually executed in the end of development.

When considering new paradigms such as the Internet of Things (IoT) and Industry 4.0 revolution, new conflicts appears between market needs and safety regulations. In this new world, the need for fast development for market fit purposes is a reality, and that´s where ASD fits (Kumari, 2018) (Laukkarinen, 2018). These challenges appear in almost all domains, such as healthcare (Gupta, 2019) (Laukkarinen, 2017).

In this context, we present a practical use case describing how was the evolution of a software product that was conceived as a wellness software for end-users in mobile platforms. The product evolved to be a medical-healthcare product, restricted to regulatory standard recommendations, where agile software practices were adopted to fulfill such guidelines.

As most Minimum Viable Products (MVP), the presented target software was firstly developed using a standard agile process. As the product requirements changed due to integration with medical devices, its regulatory requirements also increased, including the need to be complaint to standards such as ISO 82304-1 (ISO/IEC 82304, 2012) and ISO 62304-1 (ISO/IEC 62304, 2006). Therefore, the previously adopted agile methodology was adapted to fulfill these new requirements, balancing recommendations required by regulatory standards, such as requirement traceability, with agile features such as the embrace of changes.

In this chapter we show that it is possible to use standard agile methodologies in the first stages of development, when creating an MVP, and then, reuse already developed artifacts and adapt the process to be complaint with regulatory rules for safety-critical systems in the healthcare domain. The chapter shows how Scrum artifacts were adapted to enhance traceability, as also, as automated management tools were customized and integrated, and finally, how new requirements for validation and verification were introduced into the agile process due regulatory standards.

The remainder of this chapter is organized as follows: In *Background* section we present a review of agile Software Development (ASD) main features, a literature review about the main challenges in ASD for health care, and the main standards used in our work. The next section presents the adopted software development process, highlighting the main challenges and decisions made during the process adaptation. In the *Future Research Directions* section, we discuss how intelligent tools could help in software engineering process as whole. Finally, in the *Conclusion*, an overall discussion and current challenges are presented.

Background

Traditional plan-based software development processes, or disciplined processes, are based on a sequence-based linear approach, where each phase is exhaustive executed before the next one. Disciplined methodologies, such as Waterfall or V-Process (Sommerville, 2011), are usually used in the development of systems that need extensive quality assurance processes, where verification and validation activities are one of the main drivers of the product release. Although they are well suited for healthcare product development, as they usually deal with the validation of critical requirements, nowadays new market needs in healthcare demand new innovations and fast time-to-market releases. Based on this new sce-