

## The Suitability of Agile Practices in Healthcare Industry with Regard to Healthcare Regulations

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**Abstract :** Nowadays, medical devices rely completely on software whether as whole software or as embedded software, therefore, the organization that develops medical device software can benefit from adopting agile practices. Using agile practices in healthcare software development industries would bring benefits such as producing a product of a high-quality with low cost and in short period. However, medical device software development companies faced challenges in adopting agile practices. These due to the gaps that exist between agile practices and the requirements of healthcare regulations such as documentation, traceability, and formality. This research paper will conduct a study to investigate the adoption rate of agile practice in medical device software development, and they will extract and outline the requirements of healthcare regulations such as Food and Drug Administration (FDA), Health Insurance Portability and Accountability Act (HIPAA), and Medical Device Directive (MDD) that affect directly or indirectly on software development life cycle. Moreover, this research paper will evaluate the suitability of using agile practices in healthcare industries by analyzing the most popular agile practices such as eXtream Programming (XP), Scrum, and Feature-Driven Development (FDD) from healthcare industry point of view and in comparison with the requirements of healthcare regulations. Finally, the authors propose an agile mixture model that consists of different practices from different agile methods. As result, the adoption rate of agile practices in healthcare industries still low and agile practices should enhance with regard to requirements of the healthcare regulations in order to be used in healthcare software development organizations. Therefore, the proposed agile mixture model may assist in minimizing the gaps existing between healthcare regulations and agile practices and increase the adoption rate in the healthcare industry. As this research paper part of the ongoing project, an evaluation of agile mixture model will be conducted in the near future.

**Keywords :** adoption of agile, agile gaps, agile mixture model, agile practices, healthcare regulations

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