Case Study: Becoming a Medical Device Software Supplier

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***Abstract*—Today many software development companies are restructuring their business model to enter the medical device domain. The reason for this change is that significant opportunities exist within the healthcare industry and particularly in relation to the usage of software within this domain. However, in order to become either a medical device software supplier or manufacturer there are challenges to overcome. This paper describes a case study of an Irish software development company that in 2014 decided to change their business model to enable them to become a medical device software supplier. The paper provides an account of their journey from being an plan-driven automotive software supplier to securing software development contracts from leading medical device manufacturers. This involved them having to re-design and re-structure their software development approach to meet both the demands of medical device standards and medical device multinational third party software selection criteria.**

Keywords-MDevSPICE® framework; software development process; medical device software; medical device software development; agile practices; agile software development practices.

I. INTRODUCTION

In 2015, the medical device (MD) global market was "valued at $228 billion, up from $164 in 2010 and projected to reach $440 billion by 2018" "at approximately 4.4% compound annual growth rate per year" [1]. The leaders in the MD market are the US having 38% of the global value of this market followed by China with a market valued at $48 billion with western Europe having almost 25% of the global market [1]. However, to become a MD supplier for the industry takes significant time and resources as there are many obstacles that need to be overcome.

This paper presents a case study of an Irish software development company *BlueBridge Technologies* (BBT). Their journey started in 2014 when BBT decided to embark upon becoming a MD software supplier and at that moment they had no regulatory requirements in place, in fact a key question they asked at that stage was *"what are the standards we need to implement and in what order?"*. This paper presents how with the help of academic MD researchers' regulations were put in place through undergoing an MDevSPICE® assessment and outlining the challenges that might arise in the near future.

The rest of this paper is organized as follows. Section II, describes the background of BBT and the current situation in the MD industry. Section III, outlines the challenges BBT faced in order to become a MD software supplier. Section IV, describes the approaches followed to become a MD software supplier. Section V, outlines given that BBT have satisfied the regulations they wish to further refine and improve their software development processes to make them more efficient. Section VI, describes first steps taken in order to improve their current lifecycle process. Finally, Section VII provides a conclusion and future work.

II. BACKGROUND OF THE COMPANY

BTT was founded in 2006 – initially formed upon the closure of the Irish based development operations of Magna Automotive, and today employs 19 people with 8 of them working as software developers. BBT are currently working on 7 different projects with 5 of them involving developing the software component for another organization's product. Their current customers include pharmaceutical and multinational MD companies.

The main reason why software development companies wish to enter the MD domain is because of the expansion of the MD industry in the past few years therefore providing many opportunities for others to enter into this industry. The MD industry is largely research and development driven.

Software increasingly performs an essential role in the provision of healthcare services [2]. This is particularly reflected in the importance that software now plays in medical diagnoses and treatment [3]. The level of software functionality in MDs and the complexity of that software has substantially increased [4]. The MD regulatory environment has been extended to include more focus on software. For example, the latest amendment to the Medical Device Directive [5] recognizes that standalone software can be classified as a MD in its own right. Consequently, a significantly increased proportion of software applications will now be classified as MDs and must be developed in a regulatory compliant manner [6]. Medical records are increasingly being stored in electronic form. The use of Electronic Medical Record (EMR) systems in the USA by physicians increased from 18.2% in 2001 to 48.3% in 2010

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[7]. The adoption of EMR systems could produce efficiency and safety savings of $81 billion annually and improve prevention of medical diseases [8]. Use of Mobile devices in health care is increasing. "By 2017, mobile technology will be a key enabler of healthcare delivery reaching every corner of the globe" [9].

III. CHALLENGES BBT NEEDED TO OVERCOME TO BECOME A MD SOFTWARE SUPPLIER

To become a MD software supplier there were regulations and standards that needed to be adhered to. This required processes to be defined in accordance with these standards and regulations and then for objective evidence to be obtained demonstrating the implementation of the defined processes. For BBT, the starting point was to gain an understanding of three main standards. The paragraph below briefly outlines the standards that BBT familiarized themselves with before starting to define their MD software development processes.

A. ISO 13485:2006

"This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation and servicing of medical devices, and the design, development, and provision of related services" [11].

ISO 13485 is in practice necessary for any MD company. It details the requirements for the Quality Management System (QMS) for MDs.

B. IEC 62304

"This standard defines the life cycle requirements for Medical Device Software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes" [10].

IEC 62304 covers the development process for medical device software. This standard is harmonised with the requirements of ISO 13485 and therefore complements it by adding the specifics required for MD software.

However, IEC 62304 interfaces with ISO 13485 in two areas: software inputs and system integration. The software inputs are generated from the system (or subsystem) level requirements, while IEC 62304 explicitly does not cover system level activities, in particular design validation.

C. ISO 14971:2009

"This International Standard was developed specifically for medical device/system manufacturers using established principles of risk management. For other manufacturers, e.g., in other healthcare industries, this International Standard could be used as informative guidance in developing and maintaining a risk management system and process"[12]. "This International Standard deals with processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment and the environment" [12].

The area of regulatory standards and the recording of documentation associated with their implementation was new to BBT. Therefore, BBT engaged with both standards consultants and an academic research group (the RSRC, our research centre) specializing in MD software development research. This assisted BBT to fast-track the initial steps to becoming a MD software supplier.

IV. APPROACH TO BECOME A MD SOFTWARE COMPANY

When BBT reached out to the RSRC, we knew that this was an ideal company to become involved with in regards to performing research into how software companies could make the transition to becoming MD software suppliers.

A. Embark on MDevSpice® assessment

First of all, it was essential to understand BBT's current position in regards to their software development processes. We decided to perform an MDevSPICE® [13] assessment. MDevSPICE® is a framework assessment model where all MD software standards and processes are brought together into one place with software engineering best practices. MDevSPICE® was developed in the RSRC. Then, this framework assessment model was utilized in BBT to assess the current situation.

Below we describe what happened next in regards to both the assessment and BBT's subsequent journey to becoming a MD software supplier. As BBT were used to developing in a plan-driven manner and this would enable them to develop medical device software in compliance with the V-model we did not investigate agile practices at this stage.

A) Assessment conducted: Given that MDevSPICE® consists of 23 processes we selected the most appropriate 10 processes from the MDevSPICE® model to assess BBT against (see Table I).

It was agreed upon discussion with BBT that only the most foundational processes would be assessed. Therefore, the following 10 out of the 23 MDevSPICE® processes were chosen to be assessed over two onsite days at BBT.
The 10 processes chosen for the assessment were selected because they provided coverage of IEC 62304 and also provided an important system level input into the software development process. The system level process was important as BBT's software formed part of an overall medical device system comprising hardware and software and electronics. The processes were agreed upon during a meeting with senior management at BBT and the assessment team prior to the assessment. The order of the processes assessed was important as it is important to follow the medical device software development lifecycle. Therefore, systems requirements were a very natural place to start.

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TABLE I. PROCESSES OF MDEVSPICE®

MD System Lifecycle Processes	*MD Software Lifecycle Processes*	*MD Support Processes*
Project Planning	Software Development Planning	Configuration Management
Project Assessment and Control	Software Requirements Analysis	Software Release
Risk Management	Software Architectural Design	Software Problem Resolution
Stakeholder Requirements Definition	Software Detailed Design	Software Change Request Management
System Requirement Analysis	Software Unit Implementation. and Verification	Software Maintenance
System Architectural Design	Software Integration and Integration Testing	
System Integration	Software System Testing	
System Qualification Testing	Software Risk Management	
Software Installation		
Software Acceptance Support		

Below is outlined the process assessment schedule: we assessed 5 processes on each day (See Table II).

TABLE II. DAY 1 AND DAY 2 OF ASSESSMENT PROCESS

Onsite Assessment Day 1
System Requirements Analysis
Software Development Planning
Software Requirements Analysis
Software Architectural Design
Software Detailed Design
Onsite Assessment Day 2
Software Unit Implementation & Verification
Software Integration & Integration Testing
Software System Testing
Software Risk Management
Software Configuration Management

Each process was assessed by two MDevSPICE® assessors in an interview with at least two members of BBT being present in each interview. Prior to the interviews both the schedule and the names of the BBT staff members that would be involved in each process interview was agreed. It was very important to ensure that access was provided to the most relevant staff for each interview session as otherwise the assessment would not have been as accurate as possible.

Each of the 10 interviews lasted approximately one hour and involved one assessor asking BBT staff a set of scripted questions related to that process area. The second assessor used a tool to record detailed responses from the interviewees with both assessors using the tool to enable each question to be scored as “Fully Achieved”, “Partially Achieved” or “Not Achieved”. In addition to the usage of predefined scripted questions, additional questions were also asked that were specific to BBT.

B) Findings produced: The MDevSPICE® assessors at the end of Day two returned back to the RSRC and went through each process together, discusssing the observations and notes from the assessment. As a result of performing the assessment we provided BBT with a set of strengths, issues and recommendations to address those issues across each of the assessed processes.

The MDevSPICE® assessment provided coverage over a number of different MD software related standards. Figure 1 shows a breakdown of the coverage provided for each of the different standards from assessing 10 of the 23 MDevSPICE® processes. One of the key objectives of BBT Management was to gain an understanding in relation to the state of their current development processes against IEC 62304, as this is the main MD software process standard, processes were selected from MDevSPICE® that featured heavily in IEC 62304. The exception to this was System Requirements Analysis but this was deemed to be a critical process to examine as BBT would be performing software development for an overall MD system. Therefore, it is essential that they have an efficient process in place for System Requirements Analysis as otherwise everything that occurs afterwards within the development lifecycle will be impacted.

From looking at Figure 1 it can be seen that the 10 processes assessed provided: 59% coverage of IEC 62304; 2% of ISO 80002-1 [14] (this technical report relates to how ISO 14971 may be applied within software); 16% of the FDA’s Guidance for off the shelf software [15]; 1% of the FDA’s Guidance for premarket submissions [16]; 20% of the FDA’s Guidance for validation of software [17]; 1% of ISO 13485 and 1% of software engineering best practice standards.

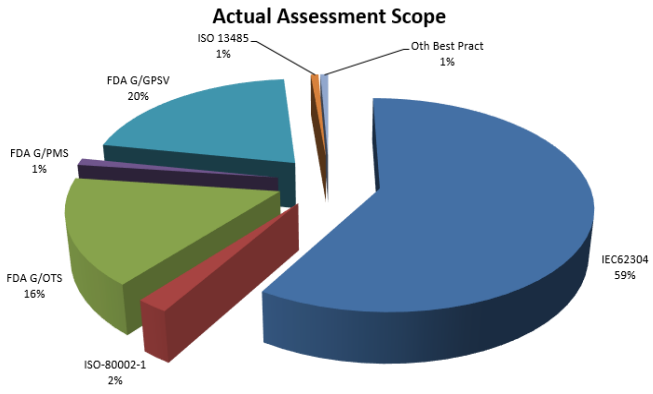

Figure 1. Scope of the BBT Assessment.

C) Implementing the recommendations: In order to assist BBT to implement the recommendations in a timely manner BBT took the following steps:

a) Brought in consultants to assist with the implementation of QMS 13485.

b) Recruited an engineer from a leading MD manufacturer who possessed considerable experience in developing MD software development and in particular MD risk management expertise to put in place a risk management strategy in line with ISO 14971.

c) Engaged with a notified body organisation to prepare them for an official audit in IEC 62304 and subsequently perform the audit. This enabled a successful IEC 62304 audit to be achieved in a timely manner.

D) Actions taken by BBT:

a) Gained Certification in IEC 62304.

b) The IEC 62304 audit was performed against one project using a plan driven approach.

c) BBT implemented the required MD standards for medical device software suppliers.

The main criteria MD manufacturers use for selecting a MD software supplier is that organizations should have IEC 62304 in place. At this stage BBT now have not only satisfied this criteria but surpassed it in that they not only adopted IEC 62304 but were certified against it and also have adopted IEC 13485, ISO 14971 and the FDA Guidance documentation for: Off the shelf software, Premarket Submissions and Validation of MD software. Therefore, at this stage BBT were ready to obtain contracts as a MD software supplier company.

V. WHAT HAPPENED NEXT?

Once BBT became a MD software supplier they noticed the significant attention within the MD field. MD software manufacturers started to get in contact and invite tenders for various projects. In fact, to date they have worked on a number of MD software development projects for different types and sizes of manufacturers. Therefore, the overhead required to implement the necessary standards was starting to pay dividends. However, now that the opportunities clearly are out there it is noticeable that BBT now want to move to the next phase of their MD software development journey and not only develop software in line with the MD standards but their ambition is now to increase the efficiency of their MD software development. Therefore, they wish to improve their software development processes even further and implement more regulatory standards in relation to security etc. The key driver to take a step further is that BBT now are undertaking challenging projects and are developing MD software for multinational MD companies they have much more to achieve in their journey. BBT have agreed to work with researchers from the RSRC to introduce MD software development best practices that will increase the efficiency of their MD software development.

A. Challenges for such large projects

However, as with every new project there are associated challenges and this is increased when embarking upon a *fixed price* project, therefore if the project is delayed or runs into some other difficulties, BTT is liable in relation to the budget. Another challenge is the *tight timeframe* where *strict milestones* have to be achieved in addition to the achievement of appropriate documentation to satisfy *regulatory deliverables*. Additionally, BBT would also like to excel in being able to *facilitate change* during the lifecycle of the project as this is something that is challenging in traditional MD software development. A very positive aspect of BBT's current approach is that they engage in regular interaction with their customers. Therefore, receiving feedback and making sure that the right MD software is developed from the very start of the development.

B. What is the current status of BBT development process lifecycle?

Currently BBT is developing software in a plan driven way through using the V-model [18]. When following a V-model the testing is planned in parallel with the corresponding development phase and the planning for verification and validation of the product is emphasized from the very beginning. To date, V-model has been proven to be the best fit when developing MD software in compliance with the regulations [19]. However, in order to improve the efficiency of their software development new software practices should be explored that have proven successful in the development of safety-critical software in association with researchers from the RSRC.

Before introducing a new lifecycle it is crucial to perform an assessment in order to establish how the current software development process should be improved/changed.

VI. ASSESSMENT PROCESS AND RESULTS

The following subsections will describe the high-level assessment process completed in BBT in 2016.

A) Assessment Process

The Software development process assessment was performed at BBT before deciding what new practices would be most suitable for BBT. We met up with the CEO of the company, project manager/developer (who had has experience of agile software development), and a developer who specialized in Android software development. The meeting was also attended by the R&D manager/Systems Risk engineer and the QMS manager. The assessment was based on previously scripted open-ended questions that related to many different areas of the company as well as the software development process.

B) Results

a) Currently BBT have several standards in place, such as IEC 62304, ISO 13485, ISO 9001 and ISO 14971. In their software development process they make use of

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various tools in areas such as project management, testing and integration. One of their main drivers for adopting new best practice software development methods is to streamline even further their already succcessful practices for interacting with customers. BBT view this as being key to delivering safe regulatory compliant software that fully meets the customer requirements and works within the intended environment, thereby decreasing the chances of expensive rework, particularly on fixed price projects.

b) Additionally, they wish to develop metrics such as problem tracking, code coverage, defects found, defects closed etc.

c) In the past, BBT was open to changes and customers were able to introduce them whenever they wanted without consequences to the overall budget, time. However, today the process has become more structured. BBT now ensures that a formal change request document is in place specifying what happens if a change occurs within a previously signed project.

d) BBT at the moment is not making use of any principle software design techniques however, they plan to introduce architecture diagrams and design patterns.

e) BBT previously have developed software in a plan driven manner and lately they have decided to integrate some agile practices into their development process..

f) Currently almost 80% of testing is automated and 20% is done manually. If the percentage of manual testing could be decreased further – the overall development process could become faster.

g) One of the team members mentioned that due to the new lifecycle approach where agile practices are introduced, there could be a challenges regarding integrating the QMS with the development process and achieving the necessary regulatory documentations.

h) At present their current process incorporates only two agile practices, they are: short iterations (every two weeks) and continuous integration.

i) BBT is also planning to provide their team with the training needed in order to work in an environment where MD software is developed in an agile way. The team will be provided with training in regards to MD software, agile practices and mobile app development.

j) Some team members will be provided with support to change towards adopting a more agile software development process.

C) Recommendations

Our advice to BBT is to integrate more agile practices into their current MD software development so that the software is developed efficiently in regular iterations and can be presented to the customer on a regular basis and facilitate change. Based upon a mini-literature review performed, the following agile practices have been cited as being used to develop software successfully for safety critical/medical domains:

a) Acceptance test-driven development (ATDD) [20].

b) Automated Tests/Automated unit testing [21].

c) Code Reviews / Peer Reviews [22].

d) Coding Standards [20][23].

e) Continuous integration (CI) [20][23][24].

f) Open Workspace [20][25].

g) Scrum [26].

h) Test-driven development (TDD) [20][27].

VII. CONCLUSION AND FUTURE WORK

This paper described a case study of a journey taken by an Irish software development company, moving from developing automotive software to developing MD software. We described how through adopting and implementing MD standards they now have become a MD software supplier. The key contribution of this research work was to enable an organization such as BBT to overcome the challenging and resource intensive learning process of understanding what standards should be put in place in order to become a medical device software supplier. Secondly, it was important to be able to provide guidance as to the order in which practices should be put in place so that previously implemented practices will not need to be overwritten later. Since becoming a MD software supplier many new opportunities have become available. However, BBT now wish to further improve their software development processes in order to become more efficient and to be able to satisfy new challenges that could rise from undertaking new multinational MD manufacturer's projects. The authors of the paper have provided a list of agile practices that have been cited to be well suitable for safety critical/medical domain.

In the future, we plan to investigate agile practices that are applicable for the MD software industry in greater detail by performing an extensive literature review and industry survey. Further, we will work with BBT to integrate the most applicable agile practices into their current software development lifecycle.

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