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Coveros Completes Agile Transformation of Safety-Critical Medical Device Company

CASE STUDY

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CHALLENGES

- Time to market is too slow
- Uncoordinated development schedules between hardware and software teams
- Significant late lifecycle rework
- Large end-of-cycle documentation and internal audit process
- Manual development, testing, and delivery process

SOLUTIONS

- Implement a cross-team agile process
- Shift team practices to agile
- Better define roles and responsibilities
- Leverage automation to accelerate tasks
- Shift software assurance activities left

Abiomed is a biomedical device company that developed the first artificial heart. The company now focuses on creating devices that provide circulatory support to the heart in surgical and emergency situations. Many of these devices are categorized as safety-critical (Class III) devices, necessitating a high level of assurance during the product development process. Abiomed was founded in 1981 and is headquartered in Danvers, Massachusetts, with an office in Aachen, Germany.

CHALLENGES

- The software organization consistently missed their deadlines and struggled to get through the development process
- Planning and resource allocation for product development was ineffective
- Device requirements changed frequently causing significant software rework
- Hardware and software teams delivery schedules were not synchronized nor coordinated
- Testing efforts were taking too long due to the manual testing process as well as the difficulty in maintaining documentation necessary for regulatory approval
- Manual build and deployment process slowed down delivery

Abiomed's product development team was working in two silos (hardware and software), resulting in significant rework for the software team when system requirements or hardware changes were made. The software organization was struggling with managing change as well as getting through their software development process in a timely manner. Late lifecycle changes were significantly impacting software testing, due to the necessity to maintain significant test documentation for FDA review and the lack of test automation. An internal audit was not integrated into the software development process, becoming a large late lifecycle hurdle to submitting to the FDA for premarket approval of devices.

SOLUTION

Coveros was retained by Abiomed to transform the organization to an agile product development process from its traditional waterfall-based methodology. This work was performed over three phases:

1. A planning phase to create a transformation plan for the organization
2. A build phase to put in place necessary agile processes and tooling and pilot agile on a medical device product development effort
3. A scale phase to spread agile concepts across the product development organization

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The overall goal was to improve quality while accelerating product development and delivery, while not adversely affecting compliance with FDA regulatory requirements.

The planning phase of the transformation consisted of several activities. The first was an assessment of Abiomed's agility using the Coveros Agility Assessment ModelTM. This model evaluates the maturity of an organization across six critical areas of agility including; an analysis of customer involvement, the organization's culture, the quality and value of produced products, strength of program/project management, the agility of software engineering practices, and overall team health. In total, our rigorous assessment model captured information on nearly one hundred elements and attributes, all of which affected the ability of the program to deliver software predictably and with high quality. Following the assessment, the organization was benchmarked against others in the industry to determine where agility gaps existed across staff skills, product development processes, and associated automation & tooling. Finally, based on our gap analysis, a backlog of transformation stories was produced to provide a prioritized roadmap for incremental agility improvement.

Following the delivery of our transformation plan, Coveros worked side by side with product teams to build and implement an agile product development process.

We started by providing Agile Fundamentals training to product development staff and company leadership. We then immediately began helping Abiomed transform its software development process from a traditional waterfall process toward an agile/iterative approach. All the while, ensuring the processes maintained compliance with FDA compliance regulatory requirements for the development of safety-critical medical device software. We developed new program roles and responsibilities, deployed agile coaches to manage software development efforts, provided technical leadership/coaching to improve software processes and artifacts. We integrated automation experts into a pilot project to work with the Abiomed software team to better automate testing, automate builds, create a DevOps delivery pipeline to support continuous testing,

and automate the generation of necessary documentation. Results delivered during the build phase of the transformation included:

1. Defined and developed an agile release planning model which included two-week development/test sprints and aligned several releases per year with the company's business rhythm.
2. Defined and developed a robust DevOps pipeline including automating the deployment of developed and tested code to the medical device embedded hardware equipment to expedite program delivery.
3. Created detailed team member roles and responsibilities which improved communication and productivity of the team.
4. Instituted a streamlined testing process that included a significant amount of automation to support iterative development. At the end of this six-month build phase, Abiomed's medical device, implemented with an agile process, was submitted and received premarket approval by the FDA.

Upon completion of our efforts to build out an effective agile process for Abiomed's software teams, we broadened our mission to further integrate software and hardware teams, incorporate business functions into the agile process, and train staff on the automation we had implemented. Additional automation was put in place to further speed the creation of necessary FDA documentation and an internal audit was integrated further into the development process. Training on the tooling and automation developed by Coveros was given to Abiomed staff and we slowly reduced our footprint until the organization was self-sufficient.

BUSINESS VALUE

Coveros was able to help Abiomed significantly accelerate its software delivery process, reducing time to market from two years to six months. Our more automated software development and testing process identified numerous safety and security issues that were effectively mitigated prior to release. The effort associated with late lifecycle internal audit review was reduced substantially as it was integrated into the day-to-day activities of the team. By automating both the traceability of requirements through tests and much of the documentation process itself, Abiomed teams are now able to focus their attention on assuring the safety and security of their products instead of documentation. Due to leveraging a more rapid development and delivery process that resulted in new products coming to market faster, Abiomed's stock rose 900% during the next two years.

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