

Accelerating Medical Device Development



Improved Team
Dynamics/Enhanced
Communication



Streamlined
Approach to FDA
Compliance



Increased
Productivity

ABOUT THE CLIENT

Our client's business focuses on developing high tech medical cardiac devices which include hardware, software, and firmware. They are subject to intense regulatory scrutiny and processes, both internally and from the FDA.

BUSINESS CHALLENGES

Managing a team of more than 50 people across the US, Canada, and India, the Director of Software Development faced significant challenges when they took over. Inheriting a group with numerous projects stuck in a perpetual state of being "almost done," releases were infrequent, happening every few years, which was far from ideal in a field that demanded more frequent updates. Adding to the challenges, the team size had recently been reduced dramatically, to around 30 people from 50.

- **Collaboration Challenges:** Teams were overly dependent upon each other, creating a complex web of inter-team communication. Accounting and management added to that complexity, inhibiting collaboration.
- **Unpredictable, Delayed Delivery:** Limited capacity planning and large releases meant major updates took years to deploy. A waterfall approach led to long, unpredictable testing and compliance phases at the end of projects, leading them to significantly - and continually - miss target dates.
- **Frequency of Releases:** Customers viewed our clients' product portfolio as old and outdated. Frequent delivery was needed to keep up with customers' expectations.

AT A GLANCE



Business Challenges

- Poor collaboration and management of dependencies
- Unpredictable, delayed delivery
- Market pressure for more frequent releases



agilityIRL Approach

- Guided team restructuring
- Conducted extensive training on Agile practices and concepts at all levels of the organization
- Coached teams consistently in Scrum and flow
- Taught and coached how to comply with FDA regulations using Agile delivery on Medical Devices



Results

- **Increased Productivity:** The team shifted from releasing every few years to every few months.
- **Improved Team Dynamics:** Aligned the teams with clear goals and coached members to engage in constructive conversations in support of those goals.
- **Enhanced Communication:** Focused teams on business objectives and outcomes, which helped to reduce dependencies. Established a framework to support cross-team communication and collaboration.
- **Strategic Support:** Challenged the team to think and operate differently, driving a cultural shift towards agility and continuous improvement. Improved leadership alignment with a new way of working.

THE APPROACH

Restructured the teams:
Guidance to align teams with product portfolio

Facilitated alignment of new approaches and processes across the organization

Coached leadership on how to further evolve an Agile transformation

Got to work!
Training and coaching to support the teams and the organization throughout the change

Trained the Teams
Interactive Scrum training, including creation of Team Working Agreements and Definitions of Done

Trained leadership to educate executives on how to effectively lead in an Agile environment

Delivered Regulatory Training to align full organization on how to achieve FDA compliance with Agile

THE RESULTS

agilityIRL highlighted the need to reconfigure teams and the planning process that **reduced dependencies, improved collaboration, and enhanced the speed of delivery** and, thus, **the flow of products to the customers**. Coaching and training around software development in the **medical device industry** (FDA TIR45) was instrumental in **revamping the Quality Management System**, in such a way that **enabled more frequent releases** (quarterly vs. annually) while maintaining the rigorous internal and external quality and regulatory standards required. agilityIRL strategically engaged and trained the leadership team, helping them to recognize and support the **significant improvements in productivity and team dynamics**. "agilityIRL made a **huge difference in how we work**," said the Software Director, underlining our contribution to the team's success.

✓ KEY BUSINESS OUTCOMES

- **Improved Quality:** By satisfying testing and documentation needs during the product development cycle, quality was built into the solution, resulting in fewer defects and a quicker pre-FDA submission process.
- **Boosted release frequency:** Reducing dependencies across teams and aligning the organization around Agile delivery improved release frequency from years to months.
- **Substantial productivity enhancements:** Through rigorous training and coaching, software delivery performance reached new heights.

WHY AGILITYIRL?

- **Agile Experts with Practical Experience:** Our ability to apply Agile principles in a real-world environment, including deep experience in regulated Agile environments. We don't position junior consultants as experts.
- **Customized Solutions:** By offering a diverse range of options rather than strictly adhering to any particular framework, we were able to customize our approach to our client's needs.
- **Trainers and Agile Experts:** agilityIRL's deep knowledge of learning is inherent in our approach and delivery. Our classes have an engaging mix of content, group discussions, and exercises that keep students engaged and able to apply concepts as they return to their work.

HOW MAY WE HELP YOU?

 Info@agilityirl.com