

From Unpredictable Releases to Faster, More Confident Delivery.



THE STORY:

How a regulated MedTech organization improved delivery speed, predictability, and learning without compromising compliance



COMPANY PROBLEM:

A growing medical technology company had a problem that will sound familiar to many MedTech leaders.

Its digital products were becoming increasingly important to customers, patients, and the business, but the development system supporting them had not kept pace.

Teams worked differently from one another. Roadmaps were difficult to trust. Capacity was hard to understand. Releases could take months after development was substantially complete, and leaders lacked a consistent view of what the organization could realistically deliver.

The company did not need another Agile rollout. It needed a better way to deliver value in a regulated environment. That distinction mattered.

AT A GLANCE



Business Challenges

- Releases were slow
- Testing and approvals accumulated late
- Too many frequent priority changes



agilityIRL Approach

- Improve the system, not just the teams
- Align Agile and quality
- Create predictable planning based on capacity.



THE CHALLENGE: GROWTH HAD OUTPACED THE DELIVERY SYSTEM

As the digital organization expanded, inconsistent practices made it increasingly difficult to predict delivery across teams or communicate realistic expectations to the business.

The symptoms were clear:

- Releases were slow and difficult to predict
- Teams had limited visibility beyond the next sprint
- Roadmaps often reflected demand more than actual capacity
- Testing, documentation, and approvals accumulated late in development
- Quality-system interpretations sometimes created unnecessary barriers
- Frequent priority changes contributed to disruption and team fatigue

The consequences reached beyond delivery efficiency. Long release cycles meant slower feedback from customers and patients, fewer opportunities to test assumptions, and less confidence across the organization that digital commitments would actually be met.



One product leader described the alternative plainly: without changing the system, releases could still be taking a year or more, with less—and potentially less important—value reaching customers and patients.

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The organization engaged **agilityIRL** because it was looking for more than general Agile expertise. It needed people who understood Agile product development in a medical-device environment and could work within the realities of quality systems, regulatory expectations, and existing delivery commitments. The work combined several reinforcing changes.

THE APPROACH: IMPROVE THE SYSTEM, NOT JUST THE TEAMS.

1



Align Agile and Quality.

Teams and Quality personnel participated in agilityIRL's Certified Agile Regulatory Specialist® training, followed by an assessment of the quality system. The goal was not to weaken controls, but to distinguish what regulation actually required from practices that had simply become customary over time. This opened the door to earlier testing and documentation, simpler approvals, and more productive conversations between Quality and development.

2



Create predictable planning based on capacity.

Team coaching was paired with quarterly planning and improved work-management practices. Teams progressed from having little visibility beyond a sprint to maintaining credible multi-quarter views of their work. Leaders could begin comparing demand with actual capacity rather than discovering problems after commitments had already been made.

3



Deliver smaller increments and learn sooner.

Instead of assuming a release had to contain everything envisioned at the beginning, teams began using MVPs and incremental delivery to get meaningful capabilities into use earlier. Feedback from pilots then influenced what came next—changing both feature priority and release sequencing based on evidence rather than assumptions. The result was not simply better Agile execution. It was a better feedback system connecting development, Quality, business leaders, customers, and patients.

THE RESULTS: FASTER DELIVERY AND MORE TRUST.

27
WEEKS



8
WEEKS

More than a two-thirds reduction.

“

Perhaps the most important result was trust.



One of the clearest improvements came in the time between feature completion and customer availability. For comparable releases, that cycle fell from 27 weeks to 8 weeks—a reduction of more than two-thirds. Testing moved earlier, quality-system practices improved, documentation became more consistent, and approval times were shortened.



Just as important, delivery became more predictable. Quarterly planning exposed risks earlier, gave teams a clearer understanding of their real capacity, and allowed leadership to see potential schedule issues while there was still time to make decisions. Major releases became more repeatable and less disruptive, with noticeably less burnout for the teams involved.



The business impact began showing up as well. A real-world MVP pilot produced strong results and gave the organization something it previously lacked: fast feedback that could immediately influence product direction.



Leaders developed greater confidence that the digital organization could deliver what it committed to. Teams gained more autonomy and focus instead of constantly reacting to shifting priorities. Portfolio conversations began evolving away from purely project-based thinking toward a more flexible view of initiatives, products, and investment.

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WHAT MADE THE DIFFERENCE:

This transformation worked because it was never treated as a Scrum implementation with a MedTech sticker on it. The organization addressed the whole delivery system: team practices, Quality, planning, tooling, leadership behavior, and the ability to learn from customers sooner. It also had meaningful executive sponsorship—something the leaders involved considered essential to achieving results beyond the individual team level.

There is an important lesson here for other regulated product organizations.



Speed and compliance are not opposing goals.

Done well, better product-development practices can improve both.

The real objective is not to “be Agile.” It is to create a system that is predictable enough for leadership, rigorous enough for a regulated environment, and adaptive enough to learn before the market—or the patient—has moved on.

**That is the kind of transformation
agilityIRL helps MedTech organizations make.**



WHY AGILITYIRL?



Agile Experts with Practical Experience:

Our ability to apply Agile principles in a real-world environment, drawing on our background as Agile practitioners was critical to support our client's Agile evolution.



Tailored Solutions:

Offering a diverse range of certified and customizable training and coaching options, we could customize the engagement according to company's unique needs and organizational culture.



Change Management Skills:

Our ability to build trusting relationships, empowering teams to succeed and be engaged, even as they navigate change.



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