

Wide Angle Agile: A Compliance-Integrated Approach to Regulated Product Development

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ABSTRACT

Wide Angle Agile (WAA) isn't just another framework; it's a necessary pivot for project management within the rigid constraints of medical device regulation. While standard Agile can stumble when faced with International Organization for Standardization (ISO) standards, WAA embeds compliance and risk management directly into the sprint cycle. This paper examines a hardware development case study to demonstrate that "broad-lens" iteration doesn't just check boxes--it actually speeds up the product pipeline by preventing the typical end-of-project documentation crisis.

INTRODUCTION

Software teams have long enjoyed the luxury of moving fast and breaking things, but in medical device development that mindset is a liability. The industry deals with firm deadlines and uncompromising regulatory gatekeepers. The traditional friction point is well-known: engineers sprint through development, only to hit a wall of documentation and risk-filing at the eleventh hour. Wide Angle Agile (WAA) fundamentally changes this internal focus. By pulling regulatory checkpoints into the daily iterative flow, WAA stops treating compliance as a post-script. It creates guardrails that allow for hardware flexibility without sacrificing the documentation necessary for a safe, market-ready product.

BACKGROUND

The project began as a hardware development workstream with a high-stakes goal: perform a series of pre-clinical studies to de-risk the eventual design down selection and verification and validation effort. In this project, requirements were not well defined at project initiation and therefore it was recognized a stage-gate Waterfall (Royce, 1970) approach would be suboptimal. Instead, we began with design specifications that were rather vague and developing, and thus constantly shifting. This resulted in a massive friction point: how do you stay agile when your deadline--a locked-in study date with a team of traveling resources--is completely immovable?

Our cross-functional group made up of engineers, regulatory leads, and clinical staff hit the classic wall of medical device development. We found an unavoidable tension between the

discipline of ISO 13485 (ISO, 2016) and the practical need to iterate. Engineering needed space to explore, but regulatory had to protect traceability and patient safety without compromise.

We leaned into the Agile Manifesto (Beck et al., 2001) to help us determine a path forward. It didn't take long to see that off-the-shelf Agile frameworks are built with software in mind, and they don't always translate well to hardware projects in regulated industries. We needed to lean on hybrid frameworks which ultimately led to the development of Wide Angle Agile (WAA). WAA goes beyond efficiency—it's a hybrid model that brings compliance, risk management, and iterative design together under one wide-angle lens. By making compliance part of the routine, not a separate track, we maintained rapid cycles while protecting the integrity of a regulated product.

PROCESS

We started by putting the team through Agile basics training to get everyone on the same page before changing our actual workflow. The first real change was a tactical one: we killed the standard hour-long weekly "all-hands" meeting and replaced it with two thirty-minute sessions. We limited these to a smaller, more specialized group to mimic a standup format. This move was all about faster decisions and more focused conversations. We tracked everything in shared OneNote files so the evolution of the format remained transparent to everyone involved.

The first few weeks were mostly trial and error. We played around with dashboards, charts, and Kanban boards, but we didn't force it. Staying true to the Agile Manifesto, we prioritized what actually worked over sticking to a rigid plan. That flexibility hit our comms, too—if a live meeting felt like a waste of time, we just swapped it for a quick update in the Teams group chat and kept moving.

Once the foundation was set, we used the first sprint to map out the core workstreams for the pre-clinical effort. These workstreams became our backlog. Interestingly, while we started with Kanban, the team eventually ditched it for an action table organized by workstream. It simply worked better for us. This table became the source of truth for deadlines and task ownership. At the end of every sprint, we held a retrospective so we could identify any friction and course correct in the weeks ahead.

The real challenge in our new approach was navigating how to integrate our ISO 13485-compliant quality management system (QMS). We could not let speed negatively impact our regulatory obligations. We remained compliant by using existing QMS artifacts to document our design changes as they happened. In practice, this meant logging updates in controlled documents and refreshing risk analyses in real-time. We maintained full traceability even when the requirements were somewhat fluid.

This hybrid framework was WAA in the real world: folding compliance and risk directly into the product development rhythm. Our program proved that you don't have to sacrifice regulatory rigor for speed. By weaving ISO 13485 requirements into the framework, we kept the team's innovation fast without compromising our design controls.

This approach was more than just a change in rules; it was a shift in how the team approached problem solving. The results extended beyond product development into cultural changes: we ended up with a group of Agile champions that were always looking for opportunities to improve our processes rather than just following a preset process. As the results spoke for themselves, skepticism about changing our way of working faded across the organization. Now, we're seeing other teams pick up the WAA model to see if they can catch the same lightning in a bottle.

RESULTS

The WAA framework delivered exactly what we needed: two pre-clinical studies completed right on schedule. This was more than just a win for the project; it proved to the team and the business that a hybrid model can handle the pressure of rapid iteration against hard deadlines without sacrificing regulatory rigor. Arguably more important than the data from the studies, we experienced a massive shift in team dynamics. Cross functional collaboration tightened, we effectively de-risked our next round of design and development, and we left the process with a core group of Agile champions ready to lead other teams in the organization.

Despite our wins, it wasn't a roaring success from the start. We experienced some friction early on, specifically with our tracking tools. We learned the hard way that while Kanban boards look good for visibility, they didn't have the teeth our team required for tracking workstreams in a regulated environment. Switching to structured action tables was the fix we needed. That being said, this sort of lesson is why one of the main components to the preliminary Agile basics training we conducted focused on adaptability. By reinforcing this openness to change early and often, the team did not hesitate much to speak up about what was working for them, what wasn't, and what they would like to try next. We made sure to give these pivots the trying change they deserved before abandoning them if the team felt they were not productive.

We also had to stay hyper-vigilant about the balance between moving fast and staying audit ready. That balance becomes a constant tug-of-war between momentum and compliance. One of the biggest takeaways on this front was how we managed communication. We realized that forcing every update into a live meeting was causing unnecessary meeting fatigue. Moving to written updates as the team felt fit through Teams gave everyone more heads-down time to work without losing alignment. These are more than just small shifts in process and execution; they are the blueprint for how we can look at applying the WAA rigor to future projects.

DISCUSSION

Applying WAA in this program gave us a clear view of both what agility can offer and where it naturally runs into limits in a regulated setting. The framework helped the team move faster, communicate better, and keep the pre-clinical studies on track. But we also had to be deliberate about how much flexibility we allowed. ISO 13485 doesn't ease up on documentation, risk, or traceability just because the team is iterating, and we couldn't treat those expectations as optional. That push-and-pull made it obvious that Agile practices can't be copied straight from software and dropped into regulated work. They have to be shaped to fit the environment. WAA reinforces that agility isn't about loosening rigor—it's about broadening the view so compliance, risk, and stakeholder clarity stay woven into every cycle of work.

Wide Angle Agile reframes core priorities for regulated environments, inspired by the Agile Manifesto:

1. Integrated compliance over end-of-project remediation
Compliance is not a phase or a checkpoint—it is part of the daily workflow.
2. Continuous risk management over delayed risk documentation
Risks are identified, assessed, and mitigated as designs evolve, not after they are finalized.
3. Stakeholder-ready documentation over sprint-only outputs
Documentation exists to support decisions, audits, and patient safety—not just velocity.
4. Adaptable structure over rigid frameworks
Processes, tools, and ceremonies evolve based on what works for a unique team in a regulated context.
5. Cross-functional ownership over functional handoffs
Engineering, regulatory, and clinical partners share responsibility for outcomes from day one.
6. Audit readiness over audit panic
Traceability and design controls are maintained continuously, not reconstructed under pressure.
7. Learning-driven iteration over blind speed
Iteration is purposeful, informed by data, risk, and regulatory constraints—not motion for motion's sake.

Both sides matter—but in regulated product development, the left is often the constraint that determines success. *This framing is inspired by the Agile Manifesto (Beck et al., 2001), adapted for highly regulated, hardware-driven product development.*

FUTURE DIRECTIONS

The experience of using WAA during pre-clinical study preparation suggests that the approach could be useful in other areas of regulated product development as well. A natural next step is to explore how it performs in verification and validation activities, where documentation expectations are even higher. There is also potential value in applying the framework across multiple programs at once, which would test how well it scales while still supporting consistency and compliance. As more organizations in highly regulated environments look for ways to innovate quickly without sacrificing regulatory discipline, WAA offers a practical model for doing both in complex, highly regulated settings.

CONCLUSION

Wide Angle Agile offers a practical way to bring agility into regulated product development without losing sight of compliance. By building risk management, documentation, and regulatory awareness into every cycle of work, teams can move quickly while still maintaining quality. This case study shows that agility and compliance aren't opposing forces; with the right structure, they can actually reinforce one another. The on-time completion of two pre-clinical studies is one example of what that balance can deliver, and it hints at the broader potential of WAA across regulated industries.

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