



PROJECT MANAGEMENT
CENTER FOR EXCELLENCE

A.J. CLARK SCHOOL OF ENGINEERING
Civil & Environmental Engineering Department

UNIVERSITY OF MARYLAND
2026 PROJECT MANAGEMENT SYMPOSIUM

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

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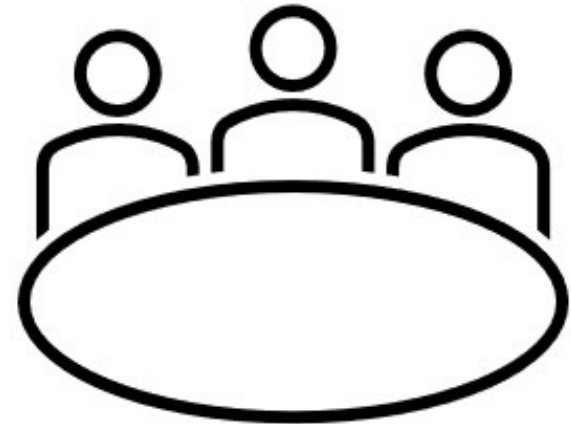
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About Me



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- Program Manager with 15+ years of experience in regulated product development
- Specializes in medical device programs governed by ISO 13485 and related standards
- Leads cross-functional teams across engineering, clinical, and regulatory domains
- Focused on integrating compliance, risk management, and documentation into agile workflows



Audience Poll



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- Familiarity with agile?
- Work in regulated hardware?

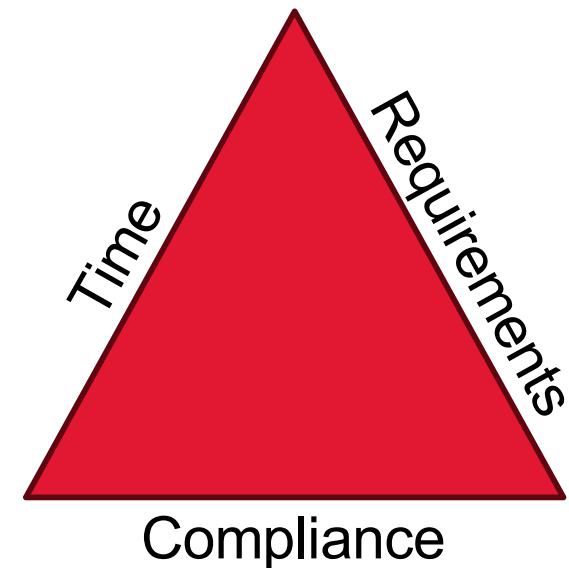


Setting the Stage: The Problem



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- Fixed study dates
- Evolving requirements
- Regulatory constraints
- The tension between rigor and adaptability



Sound familiar?

“January 15th: FDA wants data by March 1st. February 8th: Clinical team changes three requirements. February 22nd: Quality finds gaps that could delay approval by 6 months.”

The Wedding Analogy



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- It's like planning a wedding where the guest list changes every week

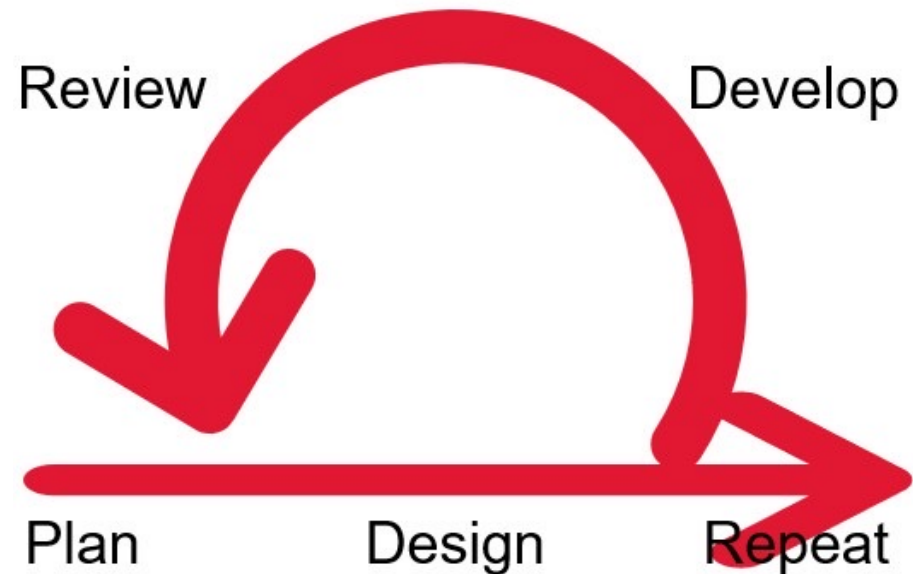


Agile Basics Refresher



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- Iteration
- Collaboration
- Responsiveness
- Why traditional agile alone doesn't fit regulated hardware



Why Agile Alone Fails in Regulated Hardware



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- Documentation bottlenecks
- Risk files updated too late
- Traceability gaps
- Compliance is treated as a phase, not a key pillar to the process

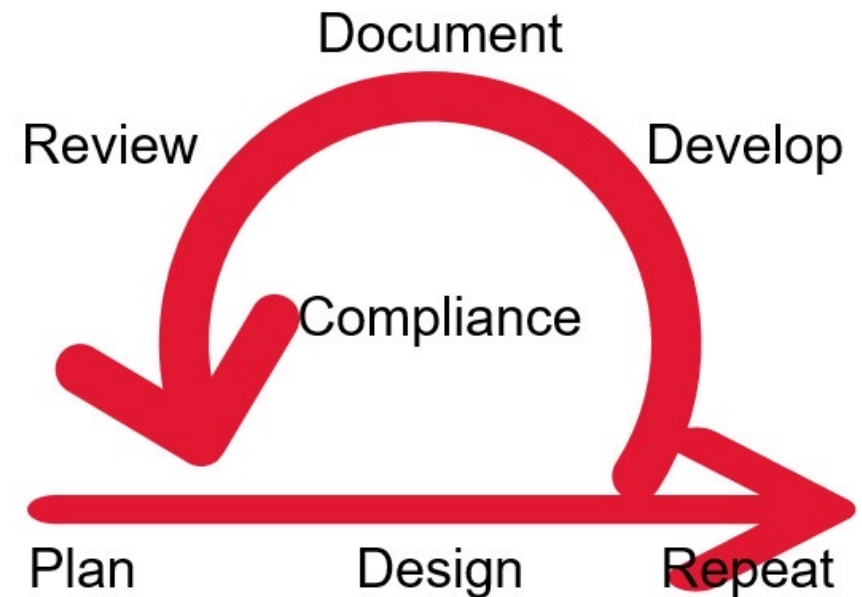


Introducing Wide Angle Agile



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- Agility with a broader lens
- Integrates compliance, risk, documentation and cross functional clarity



The Wide Angle Agile Manifesto



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Agile

- Individuals & interactions over processes & tools
- Working software over comprehensive documentation
- Customer collaboration over contract negotiation
- Responding to change over following a plan

Wide Angle Agile

- Integrated compliance over end-of-project remediation
- Stakeholder-ready documentation over sprint-only outputs
- Cross-functional ownership over functional handoffs
- Adaptable structure over rigid frameworks

WAA in Practice: Delivering Under Pressure



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- Two preclinical studies completed on schedule
- Hybrid agility supported rapid design iteration
- Cross functional collaboration strengthened
- Agile champions emerged



WAA in Practice: Learning Through Friction



- Kanban → didn't work
- Action tables → clarity and traceability
- Adaptability training paid off

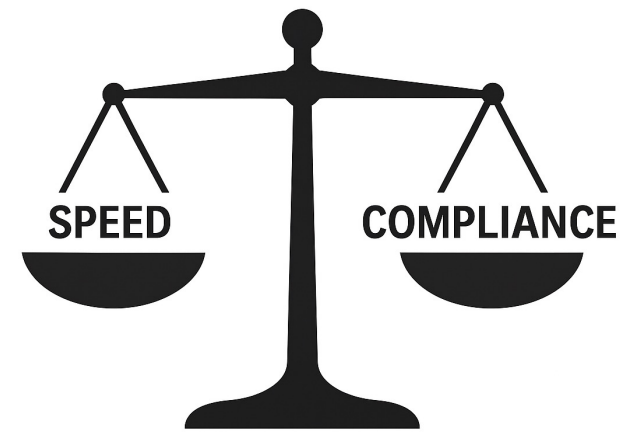
Task	Accountable	Responsible	Target Completion Date	Notes
Prototyping				
Bench Testing	Danielle	Dale	1/28/26	Prototypes due in on 1/20/26
Sterilization				
Sterilize Prototypes	Dale	Bob	2/15/26	SOW must be executed by 1/30

WAA in Practice: Balancing Speed & Audit Readiness



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- Momentum vs. compliance
- Shift to asynchronous communication
- More heads-down time to actually do the work
- Better audit readiness

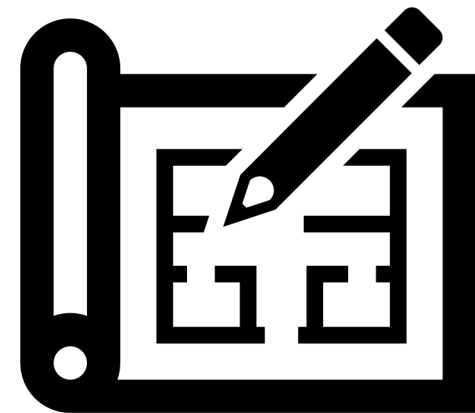


Lessons Learned



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- Adaptability is the engine of progress
- The right tool matters more than the “agile-looking” tool



Lessons Learned (cont'd)



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- Communication must evolve with the project
- Compliance must be woven in from the start



Lessons Learned (cont'd)



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- Cultural change is the real outcome
- Agile champions emerged to help drive the cultural change
- Agile without structure can be chaos; structure without agility can be stagnation



Audience Engagement Activity



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- If you could change one part of your current workflow tomorrow, what would it be?



Key Takeaways



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- Agility and compliance reinforce each other
- Adaptability is trainable
- Tools don't make you agile
- Audit readiness is a daily habit
- Cultural change is the win





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Questions & Evaluation

Evaluate Session:



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References



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