

# Applying Agile in a Regulated Setting: Balancing Flexibility and Compliance

## Presenter(s):

Jason Casavant, JD; Executive Director, Medical Writing and Quality Assurance, Synterex, Dedham, MA  
Elizabeth Patterson; Medical Writing Associate, Medical Writing, Synterex, Dedham, MA

## Introduction

Developed in 2001 as an alternative to the more rigid waterfall project management methodology,<sup>1</sup> agile project management is change-driven, focusing on fluidity and adaptability.<sup>2</sup> Agile methodologies have transformed software development and project execution by emphasizing iterative progress, responsiveness to change, and stakeholder collaboration. However, in regulated environments such as clinical trials and healthcare product development, strict compliance requirements, documentation needs, and validation processes can pose challenges to the core principles of this approach. While change-driven project management is not yet widely adopted as a primary methodology in clinical research, its potential advantages suggest it could be applied more frequently to both project execution and technology development in regulated settings.

This poster evaluates the applicability of agile, change-driven methodologies in regulated environments by identifying those principles that align with compliance requirements and those that may require adaptation, modification, or a hybrid approach to ensure regulatory adherence.

## Methods

This examination of implementation of a flexible approach in regulated settings focused on the intersection of iterative development, compliance frameworks, and risk management. Insights were drawn from industry best practices and real-world examples of adoption of agile methodologies in project execution.

## Results

*(Key Considerations for Agile in a Regulated Setting)*

An analysis of the key principles of change-driven project management revealed that some naturally align with regulatory requirements, while others may need adjustment.

### ► Principle: Face-to-Face Communication

Collaboration through frequent and routine live communication promoted team alignment during development.

- Nurtured shared understanding while avoiding delays associated with more formal communication
- Emphasized rapid decision-making, maximizing near-term impact while minimizing protracted decision-making, multiple rounds of scenario planning, and project plan revisions
- Allowed for continuous feedback, maintaining alignment over shorter-term increments

### ► Principle: Adaptability to Change

Change in projects was anticipated and welcomed as an opportunity, and teams prepared to adapt.

- Maintained compliance with regulatory change by implementing shorter workflows using a flexible, iterative approach
- Kept the focus on stakeholder needs, including those expressed in feedback from health authorities

### ► Principle: Cross-Functional Collaboration

Emphasizing team interactions over rigid processes facilitated stronger connections and greater efficiency.

- Allowed teams to self-organize to solve unique challenges encountered during the development lifecycle
- Maximized the impact of team member expertise
- Ensured that interests of compliance, operations, development, and business stakeholders were represented throughout the project cycle

### Summary of Principles That Align Well with Regulatory Settings

Traditional Approach	Agile Principle	Application in a Regulatory Environment	Positive Outcome
Predefined Requirements	Customer Collaboration	Engaging regulatory agencies and stakeholders early and often	Promotes continuous feedback
Following a Plan	Responding to Change	Iteratively responding to evolving regulatory expectations	Ensures adaptability while maintaining compliance
Process and Tool Driven	Individuals and Interactions Driven	Employing strong cross-functional collaboration	Improves compliance outcomes when paired with structured review processes

### ► Principle: Tangible Outcomes as Progress Indicators

Integrating documentation into iterative cycles allowed teams to maximize progress while achieving agility and compliance.

- Balanced competing priorities in highly regulated environments where the importance of efficiency cannot supersede that of proper documentation
- Enabled tangible outcomes (eg, reduction in time to market) to progress, even amidst significant regulatory requirements

### ► Principle: Frequent Delivery

Regular delivery of smaller components over shorter time periods while allocating sufficient time for satisfying regulatory requirements reduced expected time to completion of regulatory projects.

- Regularly providing smaller components to stakeholders reduced the review burden at end of project
- Frequent delivery of compliant components allowed for risk to be closely monitored and mitigated throughout project development

### ► Principle: Simplicity in Execution

A hybrid approach using automation and strategic planning maximized efficiency and conserved resources.

- Directed efforts to deliverables of highest strategic value and maintaining compliance
- Reduced workload by simplifying projects to deliver specific stakeholder requirements
- Promoted lean development by focusing on iterative work cycles and smaller components

### Summary of Principles That May Require Modification or a Tailored Approach

Traditional Approach	Agile Principle	Application in a Regulatory Environment	Modification Required
Comprehensive Documentation	Working Product	Rather than prioritize working products, regulated environments require extensive documentation	May need to integrate documentation into iterative cycles rather than eliminate it entirely
Delivery at Project End	Frequent Delivery	Instead of favoring rapid iteration, regulated environments require validation and controlled releases to ensure compliance with Good Clinical Practice (GCP) and other guidelines	May need to find an appropriate cadence for iteration without compromising validation
Complexity, or Maximizing Effort	Simplicity, or Maximizing Value	Despite the need for efficiency, skipping documentation or compliance steps is not feasible in a regulated setting	May need to leverage automation and strategic streamlining to maintain efficiency without sacrificing compliance

## Conclusion

Agile methodologies hold promise for regulated industries. While a fully change-driven approach may not always be feasible, organizations could consider a hybrid approach, selective modification of certain principles, or partial adoption to leverage the flexibility of change-driven methodology while ensuring compliance with regulatory requirements. As clinical research continues to evolve, the potential advantages of change-driven methodologies, such as improved stakeholder engagement, adaptability to regulatory changes, and more efficient project execution, suggest it could be more widely utilized in the future.

## Disclosures

Author(s) of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

Jason Casavant: Employee, Synterex, Inc.  
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## Citations

1. Beck K, Beedle M, van Bennekum A, Cockburn A, Cunningham W, Fowler M, et al. Manifesto for agile software development [Internet]. Agile Manifesto. 2001. Available from: <https://agilemanifesto.org/>
2. Project Management Institute. Guide to the Project Management Body of Knowledge. 7th ed. Pennsylvania: Project Management Institute; 2021.