

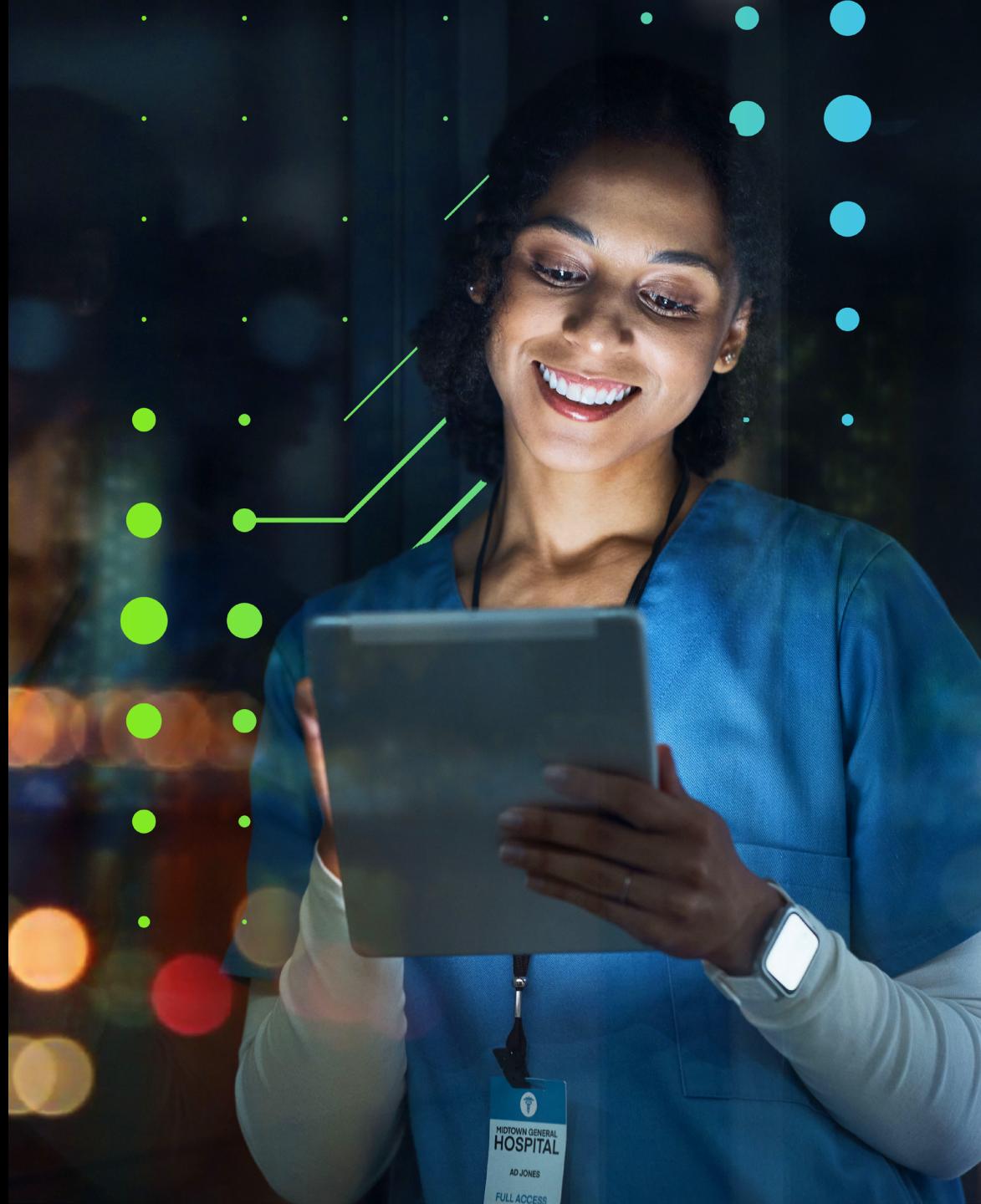
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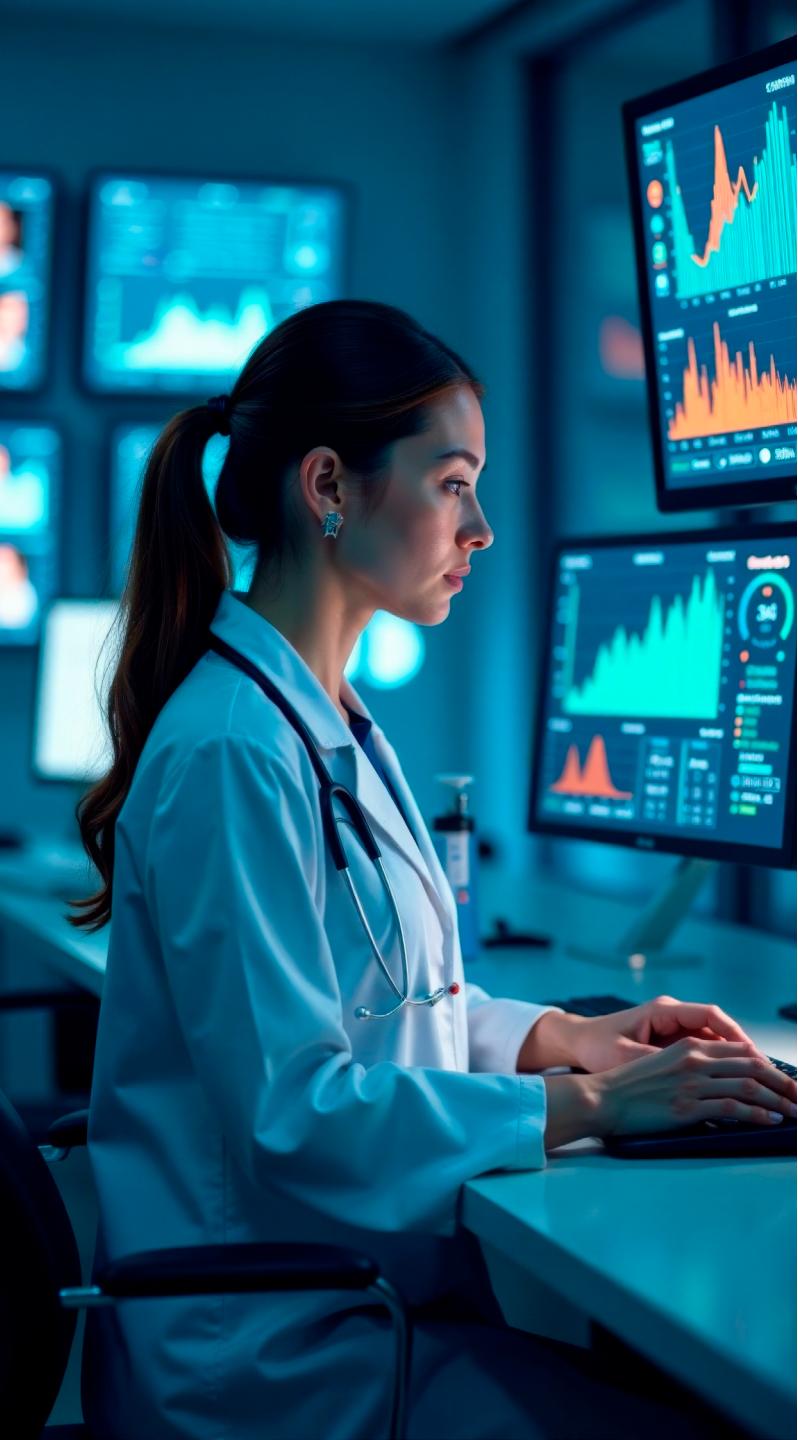


How one health care provider turned regulatory risk into a competitive edge with enterprise-wide, scaled Agile adoption

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Introduction

In today's rapidly evolving life sciences and health care landscape, organizations often face mounting pressures from intense competition, economic uncertainty, emerging technologies, and increasing regulatory scrutiny. To remain competitive and compliant, many are turning to Agile methodologies, particularly the Scaled Agile Framework (SAFe), to drive innovation, operational efficiency, and value creation across the enterprise.

Adopting Agile at scale empowers organizations to:

- **Adapt quickly:** Respond rapidly to regulatory changes, market shifts, and new technologies.
- **Enhance collaboration:** Foster cross-functional teamwork for faster, more effective problem-solving.
- **Deliver incremental value:** Accelerate product launches and improvements, reducing time to market.
- **Increase transparency:** Optimize visibility and compliance through iterative progress and regular feedback.
- **Boost innovation:** Encourage experimentation to stay ahead of competitors and evolving industry demands.

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What is the Scaled Agile Framework (SAFe¹)?

Building on the success of Agile in the technology sector, SAFe represents the next evolution of Agile methodologies by providing an effective framework for scaling Agile practices across large enterprises. With SAFe, organizations can achieve greater efficiency, alignment, and productivity by:

- Driving strong organizational cohesion and faster time to market.
- Enhancing quality and employee engagement.
- Strengthening risk management and supporting cross-functional collaboration.
- Empowering continuous improvement and enterprise-wide business awareness.

In short, leveraging SAFe empowers health care organizations to pursue continuous improvement and develop a sharp awareness of their overall business, positioning themselves for sustained growth in a competitive landscape.



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Where does risk management fit in?

Amid ongoing shifts in health care, organizations often face a maze of regulatory demands, technology transformations, and member safety concerns. Risk management (RM²)—encompassing legal, compliance, audit, and enterprise risk management

functions—plays a leading role as a trusted adviser, guiding organizations through these complexities and helping them anticipate and mitigate potential pitfalls.

But what does effective risk management truly look like for a health care enterprise embracing

SAFe? It means weaving risk awareness into every stage of transformation and empowering teams to anticipate challenges, respond quickly, and build safer, more resilient solutions for the people who depend on them.



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Case study: Scaled Agile Risk Management in action

Background

As a midsize health care company embarked on an enterprise-wide SAFe transformation, leaders quickly realized that the speed and flexibility of Agile could be a double-edged sword. Rapid iterations and frequent requirement changes, while fueling innovation, also raised real concerns about staying compliant with critical health care regulations.

For example, a routine website update, such as introducing new branding colors and imagery, may appear straightforward. However, without awareness of regulatory requirements, such as the Americans with Disabilities Act (ADA) standards for accessibility, product development teams risk inadvertently introducing compliance gaps. This underscores the need to embed risk management within Agile processes, ensuring that regulatory standards are upheld at every stage.

When Agile practices are applied unevenly across teams, whether during the initial rollout or as the new normal, blind spots can emerge. Some teams may excel at spotting and addressing risks, while others miss critical issues entirely. This patchwork approach leaves the organization exposed, with gaps in risk management that can undermine even the most well-intentioned transformation.



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Case study: Scaled Agile Risk Management in action

Approach

To help tackle these challenges head-on, Deloitte assembled a team of subject matter advisers, spanning SAFe, agile, life sciences and health care, internal audit, compliance, risk and controls, and human capital functions. By combining deep industry insight with hands-on experience, this multidisciplinary team crafted a customized strategic roadmap designed specifically for the company's risk management function, including:

1. Leadership engagement and training:

Senior leadership was educated on the impact of Agile on risk management.

Agile coaches provided targeted training for compliance, audit, and legal teams to deepen their understanding of SAFe principles and product team processes.

2. A full review of the control

environment: Existing controls were assessed for risks brought on by SAFe, and new controls were identified as needed.

3. Embedded RM interaction model into

daily practice: Regular risk assessments, risk registers, and mitigation plans were integrated into daily practice. RM touchpoints were embedded into SAFe, including ongoing stakeholder participation in Program Increment (PI3) planning sessions to help identify and address risks early and throughout the development cycle.

4. A culture of continuous improvement:

SAFe practices of regular retrospectives and feedback loops were embedded to foster a culture of continuous improvement, enabling teams to learn from past experiences and enhance their risk practices.



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Key outcomes: Enhanced risk identification, assessment, and mitigation

Embracing SAFe alongside a robust, integrated risk management approach sparked meaningful change across the organization. The results were far-reaching, delivering benefits such as:

- **Enhanced regulatory compliance:** More robust risk management practices led to improved adherence to health care regulations, reducing the risk of fines and penalties.
- **Earlier risk detection:** Program Increment planning and regular risk assessments enabled proactive identification and mitigation of risks.

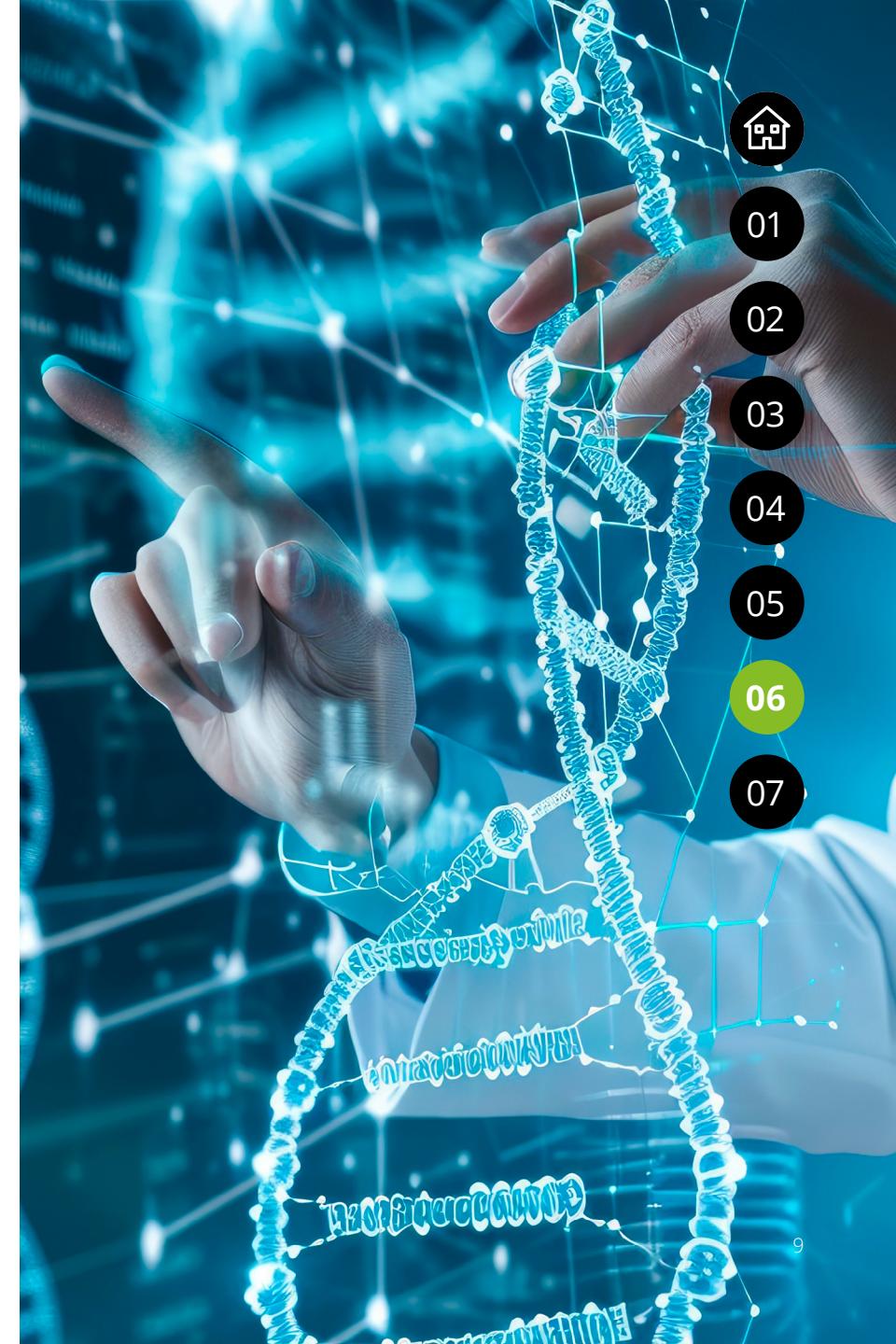
- **Continuous monitoring:** Real-time integration of risk management into the SAFe allowed for dynamic adjustment of plans and actions, leading to more effective risk oversight.
- **Enhanced collaboration and employee engagement:** Agile Release Trains (ARTs⁴) and cross-functional collaboration improved communication, risk understanding, mitigation strategies, and RM oversight. The adoption of SAFe and a risk-aware culture also boosted employee engagement and organizational control.

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Conclusion

Enterprise-wide adoption of SAFe, coupled with integrated risk management, brought about a fundamental transformation in the compliance, audit, and legal functions of the health care provider. By engaging these teams as ongoing stakeholders from the outset—and actively guiding them through the internal transformation—the organization set the stage for a successful SAFe rollout. This approach didn't just ensure alignment; it also sparked a new culture rooted in collaboration, transparency, and continuous improvement. As a result, the health care organization became far more effective at identifying, assessing, and mitigating risks.

As more life sciences and health care organizations scale Agile methodologies, weaving risk management practices into these frameworks from day one is important for achieving sustainable compliance, operational resilience, and competitive advantage.



Endnotes

1. Scaled Agile, "[What is SAFe®?](#)," accessed September 2025.
2. "Risk management" is a catch-all term for legal, compliance, audit, and enterprise risk management.
3. SAFe PI Planning is like a big team meeting where everyone comes together to plan the work for the next few months. Imagine gathering all the teams involved in a project to discuss what needs to be done, set goals, and figure out how to work together effectively.
4. In the Scaled Agile Framework (SAFe), an Agile Release Train (ART) is like a team of teams. Imagine a group of different teams working together like a train with multiple cars. Each team is a "car" on the train, and they all move in the same direction toward a common goal.



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