Rimsys Announces Rimsys AI to Eliminate Repetitive Tasks and Enhance Decision-Making for MedTech Regulatory Teams

Enterprise-grade AI built for MedTech: secure, explainable, and embedded directly into regulatory workflows

PITTSBURGH, PA, UNITED STATES, September 3, 2025 /EINPresswire.com/ -- Rimsys, the leading Regulatory Information Management (RIM) platform for the MedTech industry, today announced the launch of Rimsys AI, a suite of embedded artificial intelligence (AI) agents designed to streamline regulatory workflows, reduce friction, and empower global regulatory teams to work smarter and more efficiently.

Rimsys AI delivers secure, embedded AI agents purpose-built for the unique complexities of MedTech. While generic AI tools often operate as disconnected assistants, Rimsys AI is fully integrated into existing regulatory workflows, serving as a force multiplier for regulatory teams. Unlike competing offerings, each Rimsys AI agent operates within the Managed Context Protocol (MCP), accessing only customer-authorized data and workflows. This ensures that every output is explainable, secure, and regulatory-ready.

Key benefits include:
- Embedded intelligence within Rimsys workflows: Enables smarter authoring, review, and decision-making without leaving the platform.
- Confidence in outcomes: All AI-driven recommendations are traceable, context-aware, and aligned with industry best practices.
- Enterprise-grade security: Safeguards sensitive product and regulatory data with SOC 2 Type II and ISO 27001 certifications, ensuring customers' proprietary data is protected and meets the highest compliance standards.

Early features include:
- AI-powered Submissions that automatically reuse content across global markets, reducing time to submission by up to 90%.
- Regulatory change assessments powered by AI agents that analyze regulatory changes across products, risk classes, markets, and industry laws.
- Real-time global monitoring that continuously tracks new and changing regulations and guidances, keeping teams ahead of compliance shifts.

“With Rimsys AI, we’ve taken a fundamentally different approach than generic AI integrations,” said Jeff Burk, Chief Technology Officer at Rimsys. “Our architecture embeds AI directly into the regulatory workflows our customers use every day, which makes the intelligence contextual, trustworthy, and secure. It’s not a disconnected assistant, but an integrated force that amplifies decision-making. We’ve designed Rimsys AI to evolve with the RIM Maturity Model, so as organizations progress in their digital journey, it continuously unlocks greater automation, higher efficiency, and deeper insights.”

Rimsys AI is built to grow with customers’ digital maturity. Guided by the RIM and AI Maturity Model (see RIM Adoption as a Maturity Model), Rimsys enables organizations to realize greater value as they advance along their digital transformation journey.

Available Q4 2025
Embedded Rimsys AI features will begin rolling out to select enterprise customers in Q4 2025, with general availability planned for early 2026. Live demonstrations will be available for customers and attendees at RAPS Convergence, October 7-9, 2025.

To learn more about Rimsys AI, visit www.rimsys.io/products/rimsys-ai.

About Rimsys
Rimsys is the leading provider of Regulatory Information Management (RIM) software purpose-built for MedTech manufacturers. The comprehensive platform digitizes and automates regulatory activities, helping MedTech regulatory affairs teams to efficiently achieve regulatory compliance and get products to market faster. Rimsys is designed around MedTech workflows and supports a full breadth of regulatory functions including registrations, submissions, UDI, EUDAMED compliance, essential principles, and standards management in a unified platform. Rimsys is trusted by half of the world’s top 12 MedTech companies to power their global regulatory operations. For more information, visit www.rimsys.io.

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