

MethodSense CEO to Present at American Medical Device Summit 2025

Presentation on AI Regulation in Medical Technologies for Manufacturers, Regulators and Stakeholders

MORRISVILLE, NC, UNITED STATES, October 17, 2025 /EINPresswire.com/ --MethodSense, a leader in regulatory and quality solutions for medical device companies, is pleased to announce its participation as an exhibitor at the American Medical Device Summit (AMDS) 2025 in Chicago, IL, October 27-28. As part of this year's distinguished conference lineup, Rita King, CEO of MethodSense, will deliver a feature presentation on "Navigating FDA and EU Regulatory Landscapes for AI in Medical Technologies: Challenges and Strategies for Manufacturers, Regulators, and Stakeholders."



Feature Presentation at AMDS 2025 Monday, October 27, 2025, 12:15 pm – 12:45 pm CST, Room 1 Navigating FDA and EU Regulatory Landscapes for AI in Medical Technologies

Rita King's session will highlight:

- The latest regulatory frameworks and guidance from the FDA and the European Union, with a focus on Al-enabled medical devices and software.
- Practical comparisons of risk classification, transparency, technical documentation requirements, and post-market monitoring.
- Unique provisions under the EU AI Act, including fundamental rights evaluations, SME regulatory sandboxes, and obligations for general-purpose AI systems.
- Strategic recommendations for dual compliance, harmonizing documentation and processes, and preparing for significant EU deadlines in 2027.



Attendees will gain clarity on aligning with evolving rules, practical steps for compliance, regulatory changes that will impact business planning and submissions for Al-powered medical technologies"

Rita King, MethodSense CEO

• How MethodSense's <u>LuminLogic</u>® eQMS and comprehensive compliance management platform helps organizations efficiently manage compliance, documentation, risk management, and quality assurance in a rapidly shifting environment.

"MethodSense continues to support global medical device manufacturers with technology-driven services designed to create intrinsic value and ensure regulatory success," said Rita King, CEO of MethodSense. "Attendees will gain clarity on aligning with evolving rules, practical steps for compliance, and how regulatory changes will impact

business planning and submissions for Al-powered medical technologies."

Visit MethodSense in the AMDS Exhibit Hall to discuss solutions for Al-enabled product compliance, quality management, and process control.

For more information or to arrange a meeting during the conference, contact MethodSense at info@methodsense.com.

About MethodSense

MethodSense is a regulatory and quality consulting firm specializing in the medical device and life sciences industries. With deep expertise in FDA, EU MDR, and global regulatory pathways, MethodSense helps companies achieve compliance, accelerate market entry, and ensure product quality. Its LuminLogic® compliance management platform integrates regulatory processes, quality management, and lifecycle documentation into a seamless solution for achieving regulatory success.

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