FOR IMMEDIATE RELEASE

MethodSense Releases 2026 Regulatory Outlook for MedTech Industry

What regulatory shifts in AI, cybersecurity, digital submissions, and capital strategy mean for your success in 2026…

MORRISVILLE, NC – March 12, 2026 — MethodSense, Inc. today announced the release of its 2026 Regulatory Outlook, providing MedTech innovators, investors, and strategic partners with forward-looking guidance on the regulatory forces shaping the year ahead. As medical device companies face increased scrutiny around artificial intelligence, cybersecurity, clinical validation, and digital submissions, the 2026 Outlook delivers practical intelligence grounded in real-time regulatory engagement and submission strategy.

Key Themes in the 2026 Regulatory Outlook Include:

- **AI/ML Validation Expectations Are Maturing:** FDA expectations for algorithm transparency, dataset governance, and post-market performance monitoring continue to sharpen.
- **Cybersecurity Is Now Foundational, Not Supplemental:** Secure product architecture and lifecycle risk management are increasingly central to clearance strategy.
- **Digital Submissions and eStar Optimization:** Structured submissions are accelerating review cycles, but only when content traceability and documentation discipline are strong.
- **Investor Due Diligence Is More Regulatory-Driven:** Capital formation and exit readiness increasingly depend on demonstrable regulatory maturity.
- **Quality Systems as a Strategic Asset:** Proactive quality infrastructure reduces remediation risk and strengthens valuation.

The 2026 Regulatory Outlook reflects insights from client engagements, FDA interactions, and ongoing development of LuminLogic®, MethodSense's compliance intelligence platform.

> "Regulatory strategy in 2026 is no longer about compliance alone; it's about positioning. Companies that align clinical validation, quality systems, and capital strategy early will move faster, reduce risk, and create stronger investor confidence. Our goal is clarity. In a complex environment, companies need intelligence, not noise. The 2026 Outlook translates regulatory signals into actionable strategy."
> Rita King, CEO of MethodSense

Read the Full Outlook
The complete 2026 Regulatory Outlook is now available in the MethodSense Insights Blog**.** Read the full analysis and explore what 2026 means for your regulatory and capital strategy.

About MethodSense
MethodSense is a North Carolina–based regulatory and quality advisory firm specializing in medical device and life sciences companies. Through its advisory services and LuminLogic compliance platform, the company supports regulatory submissions, quality systems, governance, and lifecycle management across global markets. Learn more at www.methodsense.com

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