Smarteeva Announces API Integration Support for FDA's Electronic Submissions Gateway Next Generation

The company became an early adopter of a new cloud-based submission system launched in April 2025.

SOUTHLAKE, TX, UNITED STATES, May 29, 2025 /EINPresswire.com/ -- Smarteeva, a leading provider of AI-driven post-market surveillance solutions, today announced the release of enhanced product capabilities that support API submissions to the FDA's Electronic Submissions Gateway Next Generation (ESG NextGen). The FDA launched this modernized, cloud-based system on April 14, 2025, replacing legacy infrastructure with advanced API integration capabilities.

> " This is a transformative moment for regulatory compliance efficiency. The launch of ESG NextGen, with our API integration, delivers unprecedented value to our clients in the medtech sector."
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> *Plarent Ymeri, (CEO & Founder)*

The ESG NextGen platform represents a significant advancement in regulatory submissions, offering automated data exchange that improves processing speed, security protocols, and system scalability. According to industry analysis from FedTech Magazine, the new system addresses longstanding inefficiencies by eliminating outdated processes and establishing a streamlined, secure submission framework essential for today's data-intensive regulatory environment.

As an established leader in Medical Device Reporting (MDR) submissions, Smarteeva has integrated API support directly into its platform to leverage these technological improvements. The enhanced system delivers substantially faster processing times while better aligning with the complaint and adverse event reporting workflows that medical technology companies rely on daily.

Key benefits of the API integration include improved tracking capabilities for FDA

acknowledgement messages and the elimination of resubmission requirements that previously caused delays and administrative burden.

The implementation supports Smarteeva's core mission of advancing medical technology innovation through enhanced post-market surveillance capabilities. The company anticipates continued collaboration with the FDA as the industry adapts to these technological improvements.

About Smarteeva: Smarteeva specializes in AI-powered post-market surveillance solutions for the medical technology industry, helping companies maintain regulatory compliance while supporting innovation and patient safety initiatives.

Read more about us at - www.smarteeva.com

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