smarteeva

PRODUCT DATA SHEET

Smarteeva MDREngine

A cloud-based safety intelligence platform aggregating 2.6M+ global safety records. FDA MAUDE data, adverse events, registrations, and recalls in one searchable data lake with AI-powered analytics.

2.6M+	FDA	AI	Public
GLOBAL SAFETY RECORDS	MAUDE DATA INTEGRATED	POWERED ANALYTICS	API AVAILABLE

KEY FEATURES

Global Safety Intelligence in One Platform

MDREngine centralizes adverse events, device registrations, recall letters, and safety data from FDA MAUDE and global sources into a single, searchable data lake. AI-powered analytics and natural language search turn raw data into actionable safety intelligence.

01

Customized Search

Precision searches tailored to specific device names, event types, manufacturers, or time periods. Find exactly what you need across 2.6M+ records.

02

Real-Time Data Monitoring

Continuous updates from FDA and global sources. Set alerts for specific devices, competitors, or event patterns.

03

AI-Powered Analytics

Natural language processing and ML models surface trends, anomalies, and competitive intelligence from safety data.

04

Intuitive Visualization

Complex safety data translated into clear visual dashboards. Filter by device, company, event type, geography, and time.

BENEFITS

Benchmark Your Safety Data Against the Industry

MDREngine gives you the external context that internal complaint data alone cannot provide. Compare your device's performance against competitors, industry averages, and regulatory benchmarks.

Competitive Intelligence

See how your device's safety profile compares to similar products from other manufacturers.

Signal Validation

Cross-reference internal complaint trends against FDA MAUDE data to validate or dismiss emerging signals.

Regulatory Benchmarking

Understand reporting patterns for your device category across the industry.

Data as a Service

Public API lets you integrate MDREngine data into your own systems and dashboards.

Simple Adoption

Web-based interface. No installation. Rapid onboarding for quality and regulatory teams.

Risk Assessment Support

Feed external safety data into your risk management process for a complete picture.

CONNECTED TO YOUR CO

Connected to Your Complaint System

MDREngine integrates directly with Smarteeva's complaint management platform. Compare your internal complaint data against industry benchmarks in real time, inside the same system where you manage complaints.

MAUDE Integration

Full FDA adverse event database searchable and alertable

Recall Tracking

Monitor competitor and industry recalls as they happen

Cross-Reference

Overlay your complaint data against industry patterns

35%
of FDA MDRs filed through Smarteeva

70%
Faster complaint resolution

96%
First-pass extraction accuracy

50K+
Users across 80+ countries

USE CASES

How Teams Use This

Pre-Market Risk Assessment

Research adverse event history for similar devices before filing a new product submission.

Competitor Surveillance

Track safety events for competitor devices. Understand the competitive safety profile.

Signal Detection Validation

When your internal data shows a trend, check MDREngine to see if the industry is seeing the same pattern.

Regulatory Submission Support

Include industry benchmarking data in PSURs, PMSRs, and FDA submissions for context.

Why Companies Choose Smarteeva

⚙

Built on Salesforce

100% native. Enterprise security. Integrates with your CRM.

⚡

AI That's Auditable

Every AI decision has a traceable audit trail.

🔗

Connected by Design

All modules share one data model.

🌎

Any Size, Any Market

10-person startup to global top 100.

See Smarteeva In Your Workflow

30 minutes. Your use cases, your data, your regulatory markets. A live walkthrough configured for your team.

Book a Demo →

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