

## SMARTEEVA RISK MANAGEMENT

Your Solution for Enhanced Safety and Compliance

## Overview

Smarteeva's Risk Management tool is designed to offer a comprehensive and intelligent approach to monitoring and addressing potential risks associated with medical devices in the market. This tool provides medical device companies with an efficient way to manage risks, ensuring the safety and reliability of their products. The Smarteeva Risk Management solution is seamlessly integrated with all applications including the Intake and Complaints solutions enabling real-time risk assessments and subsequent risk mitigation activities.

## Key Features



**Interactive Dashboards** Manage risk with detailed, easy-to-use dashboards and reports.



FMEA/pFMEA/dFMEA



Intuitive Risk Assessments Automated tools assess risks associated with each product issue, complaint, or adverse event.



**Real-Time Analysis** Monitor device risks continuously with up-tothe-minute analysis.



**Risk analytics and risk scores** 

## Benefits



**Regulatory Compliance:** Stay ahead of regulations like the EU MDR, which emphasizes risk management.



Proactive Safety Measures: Identify and mitigate risks before they escalate.



**Access Anywhere:** Use Smarteeva on any device, making risk management more flexible than ever.



**Integration Made Simple:** Smarteeva's APIs connect all your data for unified risk management.

**Cost-Effective:** Reduce implementation costs and enjoy predictable spending.



**Detecting emerging risks** on the basis of factual evidence with AI driven risk analysis, decision trees and risk scoring.

For medical device companies looking to improve their post-market surveillance and risk management, Smarteeva offers a modern, effective solution that simplifies complex processes, saves time, and ensures compliance with industry regulations. Choose Smarteeva for a modern, comprehensive approach to risk management in the medical device industry.

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