

Smarteeva Risk Management

Integrated risk assessment connected to every complaint, adverse event, and field action. FMEA/pFMEA/dFMEA scoring, real-time dashboards, and AI-driven risk analysis built into the workflow.

<p>FMEA PFMEA / DFMEA RISK ANALYTICS</p>	<p>Real-Time RISK SCORING & DASHBOARDS</p>	<p>AI DRIVEN RISK ANALYSIS</p>	<p>EU MDR COMPLIANT RISK MANAGEMENT</p>
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KEY FEATURES

Risk Management Built Into the Complaint Workflow

Smarteeva's Risk Management tool is integrated directly with Complaints, Adverse Events, and all post-market modules. Risk assessments trigger automatically when a complaint is created. No separate system. No manual handoff.

<p>01 FMEA / pFMEA / dFMEA Full failure mode and effects analysis with severity, occurrence, and detection scoring across process, design, and system levels.</p>	<p>02 Intuitive Risk Assessments Automated tools assess risks for each product issue, complaint, or adverse event. Scoring happens inside the record, not in a separate spreadsheet.</p>
<p>03 Interactive Dashboards Real-time risk dashboards with drill-down by product, complaint category, geography, and time period. Updated as data changes.</p>	<p>04 AI-Driven Risk Scoring Machine learning models detect emerging risk patterns from factual evidence. Decision trees and risk scoring adapt as new complaint data arrives.</p>

Why Risk Management Belongs Inside PMS

When risk management sits in a separate system, quality teams spend time copying data between tools instead of acting on risks. Smarteeva eliminates that gap.



Regulatory Compliance

EU MDR requires risk management integrated into PMS. Smarteeva makes that integration structural, not manual.



Proactive Safety

Identify and mitigate risks before they escalate. AI surfaces patterns that manual review misses.



Connected Workflow

Risk scores update automatically when complaint data changes. No re-entry. No version conflicts.



Access Anywhere

Web-based, any device. Risk reviews happen where your team is, not where the server is.



Cost-Effective

No separate risk management license. Built into the platform. Predictable spending.



Audit-Ready

Full traceability from complaint to risk score to mitigation action. Every step logged.

RISK INTELLIGENCE

Risk Intelligence, Not Just Risk Tracking

Smarteeva goes beyond static risk matrices. AI analyzes complaint patterns across product codes, geographies, and time periods to surface emerging risks that manual trending would miss.

Adaptive Thresholds

Alert when incident rates deviate from baselines

Cross-Product Analysis

Compare risk profiles across your portfolio

Signal to Action

From detection to CAPA trigger in one system

35%

of FDA MDRs filed through Smarteeva

70%

Faster complaint resolution

96%

First-pass extraction accuracy

50K+

Users across 80+ countries

How Teams Use This

Complaint-Triggered Risk Review

Every new complaint automatically triggers a risk assessment using pre-configured scoring criteria for the affected product family.

Trend-Based Risk Escalation

When complaint frequency for a product exceeds the rolling baseline, the system flags it for quality team review.

Audit Preparation

Pull complete risk history for any product, showing every assessment, score change, and mitigation action with timestamps.

Cross-Functional Risk Dashboards

Quality, clinical, and manufacturing teams share one risk view. No conflicting spreadsheets.

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.

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