WHITE PAPER

Transforming Medical Device Post-Market Surveillance

How Smarteeva replaces manual complaint handling, disconnected systems, and spreadsheet-based risk management with one AI-powered platform built for the entire PMS lifecycle.

20%
ANNUAL INCREASE IN DEVICE COMPLAINTS

42%
AVERAGE ANNUAL INCREASE IN RECALLS

35%
OF FDA MDRS FILED THROUGH SMARTEEVA

8 min
PSUR GENERATION TIME

smarteeva

THE CHALLENGE

Post-Market Surveillance Is Under Pressure From Every Direction

In the last decade, medical device complaints have increased 20% annually. Recalls have risen 42% on average each year over the past five. High-profile cases like the Philips CPAP recall and textured breast implant investigations have put complaint management under intense public and regulatory scrutiny. EU MDR has tightened reporting obligations. FDA is pushing for real-world evidence and earlier risk detection.

Most PMS teams are caught in the middle. They run on manual data recording and processing, with a narrow focus on compliance. The 20% annual increase in complaints and MDRs, combined with new international regulations, keeps adding to the workload without adding headcount.

Where Teams Are Stuck

Post-market surveillance teams spend the majority of their time on basic data collection. Risk assessment, product improvement, and patient safety analysis get squeezed out. Risk management is rarely integrated into complaint handling systems because of organizational silos and the limitations of current QMS platforms. Self-service capabilities for customers and field teams are almost nonexistent, representing a missed opportunity for structured data capture at the source.

THE SMARTEEVA INITIATIVE

Built From Day One for Post-Market Surveillance

Smarteeva was founded with a specific vision: to move beyond data entry and form-filling. The platform was designed to be an operational partner for PMS teams, capable of guiding and even handling complete post-market surveillance activities. The mission is to reduce risk for device companies while transforming how they execute PMS processes.

Unlike QMS platforms that treat PMS as a secondary module, Smarteeva was purpose-built for the full post-market lifecycle: complaint intake, adverse event reporting, recall management, regulatory submissions, risk management, and product registration. Every module shares one data model and one AI engine.

THE SMARTEEVA SOLUTION

Five Capabilities That Change How PMS Works

Smarteeva addresses the structural problems in complaint handling and post-market surveillance with five integrated capabilities:

1. Integrated Risk Management

Risk assessment is built into the complaint workflow, not bolted on from a separate system. Every complaint triggers a risk evaluation using FMEA/pFMEA/dFMEA scoring. Risk scores update in real time as complaint data changes. Quality teams see risk in context, not in a separate spreadsheet.

2. Smart Complaint Templates

AI-powered templates automate data entry and pre-fill complaint records from incoming sources. 96% first-pass extraction accuracy. Records that took 15+ minutes to create now take under 60 seconds. Duplicate detection catches 95% of redundant entries before they enter the system.

3. Similar Record Functionality

When a new complaint arrives, Smarteeva surfaces similar historical records. Quality teams see how comparable complaints were investigated, coded, and resolved. This speeds decision-making and improves consistency across the team.

4. Automated Regulatory Reporting

MDRs, MIRs, CVRs, PSURs, and 80+ country-specific regulatory reports generated from within the platform. Direct FDA ESG NextGen API submission. EU MDR vigilance reporting. 3-minute MDR submissions. 8-minute PSUR generation. No manual assembly from fragmented data sources.

5. Integrated Data Lake with AI

MDREngine aggregates 2.6M+ global safety records for benchmarking and cross-referencing. Natural language search provides answers to complex queries across your internal data and industry databases. AI-powered signal detection flags emerging patterns before they become recalls.

70%	96%	95%	1 in 5
Faster complaint resolution	First-pass extraction	Duplicate detection rate	FDA recalls on platform

CONCLUSION

The Future of PMS Is Already Here

The medical device industry faces a structural mismatch: complaint volumes are rising, regulatory requirements are tightening, and most PMS teams are still running on manual processes built for a fraction of today's workload.

Smarteeva closes that gap. By automating complaint intake, integrating risk management into the workflow, and connecting every module through one data model and one AI engine, the platform transforms PMS from a compliance burden into an operational advantage.

The data to improve product quality, reduce risk, and satisfy regulators already exists inside every device company. The question is whether your system can act on it. Smarteeva was built to be that system.

What Sets Smarteeva Apart

PMS-First Architecture	**Auditable AI**	**One Data Model**	**Global Scale**
Not a QMS with PMS bolted on	Every decision traceable	Complaints to CAPA connected	80+ countries, 50K+ users

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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