

Smarteeva PMS Reporting

Automated PSUR, PMSR, HCSR, PMCF-ER, and PMPF-ER generation. Data aggregation from complaints, investigations, and external sources. AI-assisted content generation. Wave scheduling and multi-section workflow.

8 MIN PSUR GENERATION	5 REPORT TYPES SUPPORTED	AI CONTENT GENERATION	Wave SCHEDULING & ALERTS
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KEY FEATURES

Every PMS Report, One Automated Workflow

Smarteeva generates PSUR, PMSR, HCSR, PMPF-ER, and PMCF-ER reports from a single system. Data is pulled automatically from complaint records, investigation outcomes, external safety databases, and sales/distribution data. Templates are customizable. AI assists with content drafting. Wave scheduling keeps teams on deadline.

01 Automated Data Aggregation Pull data from ERP systems, complaint handling, recall databases, and external sources. Re-query anytime. No manual data assembly.	02 Customizable Report Templates Business users create and manage templates with custom tables and charts. Each template has its own review, approval, and versioning workflow.
03 AI Content Generation Pre-integrated LLMs generate content summaries, draft sections, and populate report fields directly from within the system.	04 Wave Scheduling & Alerts Set wave dates for reporting cycles. Automated notifications alert PMS owners 60 days out and content creators 30 days before the wave begins.

From Weeks of Manual Assembly to Minutes

Most PMS teams spend weeks assembling regulatory reports from fragmented data sources. Smarteeva reduces that to minutes by automating data aggregation, template population, and section management.



Product Segmentation

Group licensed products by risk class, jurisdiction, and regulatory type. Reporting frequency auto-calculated per EU MDR/IVDR rules.



Multi-Section Workflow

Multiple content creators work on separate sections independently. Each section has its own review and approval cycle.



Jurisdiction Mapping

Risk class, report format, and periodicity mapped automatically per regulatory requirements (EU, Canada, FDA).



Material Grouping

Products with similar traits grouped for reporting. UDI-DI based grouping supported.



Finalization & Validation

2-5 reviewers per report type. Discrepancies flagged and sections reopened until resolved.



8-Minute PSURs

What used to take hours of manual assembly now generates in minutes with verified data.

AI-POWERED REPORT DR

AI-Powered Report Drafting

Smarteeva's Smart Template feature works with integrated LLMs to auto-populate report sections, generate trend summaries, and draft benefit-risk analyses. Content creators start with a working draft, not a blank page.

Auto-Population

Fields filled from live complaint and investigation data

Trend Summaries

AI generates complaint trend narratives per product group

Review Workflow

Built-in approval chain with version control

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

EU MDR PSUR Generation

Auto-generate PSURs for Class IIa/IIb/III devices with data pulled from complaints, CAPAs, and external safety databases.

Health Canada HCSR

Produce Health Canada Safety Reports with jurisdiction-specific formatting and periodicity rules.

PMCF Evaluation Reports

Compile post-market clinical follow-up data from surveys, registries, adverse events, and literature into structured PMCF-ER reports.

Multi-Product Wave Scheduling

Schedule reporting waves across your entire product portfolio. Notifications keep every content creator and reviewer on track.

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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