Case Study

Smarteeva has fully automated the generation of reports such as EU PSUR, UK PSUR, EU PMSR, UK PMSR, PMPF-ER, and HCSR, which previously required more than 100 hours to complete. This automation significantly boosts efficiency while ensuring compliance.

ABOUT MEDICAL DEVICE CUSTOMER

A global biotech leader and top in-vitro diagnostics provider was dedicating excessive time to labor-intensive, inefficient post-market surveillance reporting, with planning and risk assessment cycles lasting nearly half a year.

OPPORTUNITY

Quality processes suffered due to unautomated PMS report generation lacking LLM integration, compounded by slow data transfer systems that lacked scalability for future needs.

- The lack of a centralized system caused sales, incident, and complaint data to remain isolated across teams, hampering process efficiency.
- The legacy system, such as the Medical Device Regulation (MDRs), was limited to FDA database information. This necessitated manual searches for competitor device data and regulatory reports from international sources, including Health Canada and other global authorities.

- Projects were manually created and assigned, leading teams to track everything in Excel. Without structured data inputs, content creators frequently inserted generic statements, compromising accuracy.
- The planning and risk assessment phase required a six-month implementation cycle to ensure comprehensive evaluation.
- Organizational changes among content team members triggered cumbersome manual workflows for section reassignment.

SOLUTION

Smarteeva's Post-Market Surveillance (PMS) and Complaint Management solution was designed to address the full scope of regulatory compliance, ensuring adherence to international reporting requirements across all risk classes, not just complaint documentation. Where manual processes once consumed 100+ hours across disjointed emails, conflicting versions, and error-prone spreadsheets, Smarteeva now delivers identical outcomes in just 8 minutes - achieving 95% automation, perfect accuracy, and complete digital audit trails.

- Smarteeva automated the complete PMS report generation lifecycle for reports such as EU PSUR, UK PSUR, EU PMSR, UK PMSR, and HCSR, along with the integration of related reports like PMPF-ER.
- Before, teams had to check multiple systems to see where products were approved. Now, a single map shows all approvals across the UK, Canada, and Europe using real data instead of guesswork.
- With Smarteeva's intelligent classification engine, products are instantly matched to their EU/UK risk category (A, B, C, D for IVDR and I, IIA, IIB, III for MDR and I, II, III, IV for CA) based on predefined regulatory rules. The system calculates exactly how often reports are needed - all without manual input.
- The system automatically calculates when your next reports are due by identifying the licensing date and checking device risk classification and checking your device's risk level. No more manual calendar tracking.
- Smarteeva's system auto-generates project plans seven days before they're needed. This gives teams a clear, organized way to check and improve their work before they start gathering data.
- During implementation, the Smarteeva platform automatically extracts critical metrics from Snowflake's data warehouse, including sales volume, serious incident reports, CAPA records, and customer complaint data

- Smarteeva streamlines documentation by auto-filling empty sections (e.g., CAPA fields) with compliant default text (e.g., 'No CAPA required') and auto-closing them. Standardized data fields are similarly auto-filled, significantly reducing manual effort for content creators.

- Smarteeva platform dynamically generates executive summaries, key findings, and conclusions through rule-based automation, ensuring every document meets quality standards and is ready for audits.

- Once all sections are completed, the system automatically initiates a two-step approval process that includes digital signatures. To ensure accuracy, reviewers can reject submissions or reopen individual sections for corrections before final approval.

- Users can configure report templates with custom fields, table formats, and empty-data alerts. No manual chasing, no missed deadlines.

- The platform then auto-generates PMPFRs 13 days pre-project, with smart sync features that keep reports updated as projects evolve.

- Smarteeva's clickable table of contents simplified report navigation, and section previews let creators verify formatting pre-submission. These intuitive features help teams, regardless of experience level, create compliant reports faster than ever.

RESULT

Holistic Reporting: AI-Generated PMS Reports in Minutes.

- Smarteeva’s automated document management system replaced error-prone Excel tracking with a centralized platform, significantly enhancing efficiency. The solution provides real-time visibility and enables quick redistributions through its intuitive section reassignment feature, completed in just a few clicks. Automated email alerts ensure timely escalations for overdue sections, eliminating delays while improving accuracy, cost savings, and compliance.

- At Smarteeva, we are committed to delivering continuous value through AI-driven innovation, transforming complaint management systems (CMS), and optimizing medical device reporting. This advancement underscores our mission to redefine post-market surveillance with intelligent automation.