smarteeva

POST-MARKET SURVEILLANCE (PMS) REPORTING

THE SMARTEEVA SOLUTION

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The Overview

Post-Market Surveillance (PMS) reporting ensures the ongoing safety, performance, and quality of medical devices after they enter the market. It goes beyond compliance, allowing manufacturers to improve product design based on actual clinical use, ensuring devices remain safe and effective for broader populations.
In PMS, the system generates critical reports to comply with regulatory requirements, including:

- PSUR (Periodic Safety Update Report)
- PMSR (Post-Market Surveillance Report)
- HCSR (Health Canada Evaluation Report)
- PMPF-ER (Post-Market Performance Follow-up Evaluation Report)
- PMCF-ER (Post-Market Clinical Follow-up Evaluation Report)

The system facilitates report planning and organization, enabling licensed products to be grouped and managed in phases for smooth submissions.

Key Features

1. **Automated data aggregation from multiple sources:** The PMS Reports system simplifies the process by aggregating data from ERP systems, complaint handling systems, and recall databases. Reports are generated based on product groups and reporting dates, with the ability to re-query data whenever necessary.
2. **Customizable templates for reports:** Business users can easily create and manage report templates, customizing tables and charts for their reports. The template creation process includes its own review, approval, and versioning workflows. Examples include PSUR, PMSR, HCSR, PMPF, and PMCF templates, with no restriction on the number of templates that can be created.
3. **Integrated AI for automatic content generation:** Smarteeva comes pre-integrated with large language models (LLMs), enabling it to provide content summaries or help creators generate content directly from within the system.
4. **Automated Text Generation:** Smarteeva's Smart Template feature simplifies automated content population, enabling business users to create and manage templates effortlessly for various sections of reports.

5.**Wave functionality for scheduling reports:** A Wave refers to a set date for initiating reporting for licensed products. Smarteeva's wave functionality include key features such as:

- Ability to choose wave date, month, and assign a custom name.
- Validation to prevent overlapping wave dates.
- Custom notifications alert PMS Owners 60 days and Content Creators 30 days before the wave begins.

Benefits

1. **Product Segmentation:** Product Grouping acts as the main entity for organizing licensed products in regulatory submissions. It:

- Combines different licensed products logically for reporting to health authorities.
- Establishes the risk class, which determines reporting frequency in line with regulatory requirements.

2. **Jurisdiction and Risk Class Mapping:** The Smarteeva system organizes risk classifications, report formats, and periodicity based on jurisdictional requirements. The following example shows how reports are aligned with risk classes and jurisdictions.

Jurisdiction	Risk Class	Report type name	Type - PMPF/PMCF	Periodicity (years)
EU	EU IVD Class A	PMSR_IVD_{{ Product Group }}	Q_PMPF-ER	5
EU	EU IVD Class B	PMSR_IVD_{{ Product Group }}	Q_PMPF-ER	3
EU	EU IVD Class C	PMSR_IVD_{{ Product Group }}	Q_PMPF-ER	1
EU	EU IVD Class D	PSUR_IVD_class_D_{{ Product Group }}	Q_PMPF-ER	1
EU	EU MD Class I	PMSR_MD_{{ Product Group }}	Q_PMPF-ER	3
EU	EU MD Class IIa	PSUR_MD_{{ Product Group }}	Q_PMPF-ER	2
EU	EU MD Class IIb	PSUR_MD_{{ Product Group }}	Q_PMPF-ER	1
EU	EU MD Class III	PSUR_MD_ClassIII_{{ Product Group }	Q_PMPF-ER	1
CA	CA Class IV	HCSR_{{ Product Group }}	not due	1
CA	CA Class III	HCSR_{{ Product Group }}	not due	1
CA	CA Class II	HCSR_{{ Product Group }}	not due	2
CA	CA Class I	no assignment to a report needed	not due	

3. **Material Groupings:** Smarteeva's Material grouping functionality allows **Licensed products** with similar traits to be organized into material groups for reporting. Grouping products by similar numbers or classifications. Creation of concise, organized reports that streamline compliance efforts. The system groups materials based on attributes like material numbers and Basic UDI-DI. For Example:

- If two devices share the first 8 digits of their material number, they are grouped, with the lowest number taking the lead.
- Devices with the same Basic UDI-DI are grouped, with the highest number becoming the lead device

4. **Sections:** With Smarteeva's Section functionality, multiple content creators can work on separate sections of a report independently. Each section undergoes its own review and approval process, and once approved, the entire report is ready for finalization.

What are Sections?

Sections in a report contain vital data, such as sales volumes and complaints, intended for regulatory authorities. They also feature Benefit-Risk Analysis and conclusions. Sections are organized into phases, with later ones—like the Executive Summary—relying on earlier sections. Reports may have two or more phases, based on their complexity.

What are Licensed Products?

Licensed products are those officially registered with health authorities.

* Products can hold multiple licenses within one jurisdiction.
* Each product tracks compliance with Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR).

Outlining the Smarteeva Project Stages:

1. **Project Initiation:** The initial step in Smarteeva's PMS Reporting workflow involves project creation for product groupings based on reporting regions (e.g., EU or Health Canada) and regulatory type (IVDR or MDR). IVDR products generate PSUR and PMPF-ER reports, and MDR products generate PMSR and PMCF-ER. Projects are initiated 60 days before the wave start date, with email notifications sent to users.

2. **Section Allocation & Alerts:** The second step starts when Content Creators are alerted to begin Phase 1 sections on the project start date. Each section has a set due date, with reminders and overdue notifications sent if deadlines are missed.

3. **Approval and Validation Process:** Once all phases are completed, the project enters Finalization. Reports are reviewed by 2 to 5 users, depending on the type. If discrepancies are found, sections are reopened for corrections. This process repeats until all discrepancies are resolved. After a successful review, the project is marked complete, and the final report is stored for submission to regulatory authorities.

Conclusion

Smarteeva's functionality transforms PMS reporting by automating the entire process, from data preparation to final report submission. The platform's ability to aggregate data from multiple sources, manage templates, and automate text generation significantly reduces manual effort and improves the accuracy of regulatory submissions. With its built-in notifications, section assignments, and finalization workflows, Smarteeva ensures that every aspect of PMS reporting is handled efficiently and on time. Smarteeva's project workflow not only boosts productivity but also enhances compliance by making PMS reporting simple, transparent, and fully automated.