Laborie

How Laborie unified global product registration across diagnostic and therapeutic devices.

2 Lines
DIAGNOSTIC + THERAPEUTIC

Global
REGISTRATION COVERAGE

510(k)+
SUBMISSION TYPES MANAGED

ERP
INTEGRATED PIPELINE

About the customer

Laborie is a global medical technology company that manufactures both diagnostic and therapeutic products. The breadth of their portfolio — spanning two distinct product lines, each with different regulatory pathways and registration requirements — made tracking the entire portfolio in a single application a persistent challenge, both in cost and maintenance.

Industry MedTech — Diagnostic MedTech — Diagnostic & Therapeutic Therapeutic (Laborie)

Challenge

Laborie manufactured both diagnostic and therapeutic medical devices — two product lines with different regulatory pathways, different registration requirements, and different health authorities around the world. **Tracking all of this in one system was considered unthinkable.** So they didn't. They used spreadsheets.

The previous registration software restricted product tracking and couldn't handle submissions to global regulatory authorities.

Pain point	Spreadsheet-based registration
Key outcome	Unified global registration
Platform	Salesforce + ERP integration

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We'll walk you through Smarteeva with your use cases, your workflows, and your data.

Email address

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The RA team filled the gap with manual workarounds that consumed time, introduced errors, and created compliance risk at every turn.

- Multiple spreadsheets with no cross-linking. Product registrations lived in spreadsheets that weren't connected to documentation or country requirement templates. Maintaining this manually was unsustainable and time-consuming — and there was no way to verify that the data was current or complete.
- Expiration dates tracked without automation. Individual product expiration dates were tracked manually. Without unified automation, the RA team had no systematic way to know when renewals were due — let alone which country-specific actions those renewals required. This disrupted the entire end-to-end process.
- Registrations, licenses, and regulatory impact assessments in one app — impossible. Managing product registrations, licenses, and regulatory impact assessments across the entire product portfolio in a single, global application was beyond the capability of the previous system. The RA team operated across fragmented tools with no unified view.
- No direct submission capability. The previous system couldn't support direct submissions to health authorities. Every submission required manual compilation, formatting, and delivery — adding time and risk to every regulatory interaction.

> *"Managing two product lines across global regulators through spreadsheets wasn't just inefficient — it was unsustainable. We needed one system that could handle*

> *diagnostic and therapeutic registration pathways without compromising on either."*

Approach

Smarteeva's approach started with the recognition that Laborie's challenge wasn't just registration tracking — it was the complete absence of a unified system that could handle two distinct product lines, multiple submission types, and global regulatory coverage without reverting to spreadsheets.

The implementation was designed around three priorities:

- One application for both product lines. Diagnostic and therapeutic devices have different regulatory pathways — 510(k), pre-market, and post-market submissions all follow different rules. The platform needed to handle all of them without forcing the RA team to switch between tools or maintain separate tracking systems.
- ERP integration as the data backbone. Product catalog data lived in Laborie's ERP. Registration data lived in spreadsheets. The two needed to be connected through a live pipeline — not through manual exports and imports — so that every product change in the ERP was automatically reflected in the registration records.
- Automated submissions and dashboards. The RA team needed to stop compiling documents manually and start generating regulator-ready outputs with a click. Real-time visibility into registration status, expiration dates, and submission progress was non-negotiable.

Solution

Smarteeva implemented a product registration system that unified Laborie's entire portfolio — diagnostic and therapeutic — in one platform with ERP integration, automated submissions, and real-time regulatory visibility.

1. **Unified registration across both product lines.** Diagnostic and therapeutic products now share one registration platform. Product categorization, expiration dates, registration status, and country requirement groups are all managed together — eliminating the need for separate spreadsheets and tracking systems for each product line.

2. **Data quality through deduplication.** Smarteeva improved data quality across the registration database by identifying and reducing data duplicates and discrepancies. The RA team now works from clean, consistent records instead of reconciling conflicting spreadsheet versions.

3. **Faster response to health authorities.** Smarteeva's registration management system established a faster mechanism for responding to health authority inquiries and requirements — with tracking features that ensure nothing falls through the cracks and no deadline is missed.

4. **Multi-format submission support.** Depending on the submission type — 510(k), pre-market, post-market — the system allows users to create, review, and send all related documents to global authorities directly from the platform.

PDF, Word, XML — whatever the regulator requires.

5 Real-time visibility through dashboards. Smarteeva gave the RA team complete, real-time control over the progress of every regulatory submission through intuitive reports and dashboards. The days of checking spreadsheets to understand registration status are over.

6 ERP integration pipeline. A continuous integration pipeline connects Laborie's ERP with Smarteeva, ensuring product catalog data stays synchronized. Manufacturing changes, new product additions, and catalog updates flow automatically into the registration system — no manual data entry.

7 Country-specific automation. Registration workflows, templates, and requirements are configured by country. When a product needs to be registered in a new market, the system generates the correct template, applies the correct regulatory rules, and tracks the submission through the correct approval pathway.

Results

The spreadsheets are gone. **Both product lines — diagnostic and therapeutic — now run on one unified registration platform** with ERP integration, automated submissions, and real-time visibility across every market.

- Spreadsheets → one governed system. Product registrations that lived in disconnected spreadsheets now run on a

single platform with version control, automated tracking, and a complete audit trail.

- Two product lines, one registration workflow. Diagnostic and therapeutic devices — previously tracked in separate systems — now share one registration application. The RA team manages the entire portfolio without switching tools.
- Direct submissions to global authorities. 510(k), pre-market, and post-market submissions are created, reviewed, and sent from the platform — in the format each regulator requires. No more manual compilation.
- Real-time registration visibility. Dynamic dashboards and automated reports give the RA team instant visibility into registration status, expiration dates, and submission progress across every product and every market.
- ERP-synchronized product data. The continuous integration pipeline means product changes in the ERP are reflected in registration records automatically — eliminating the data lag that previously caused missed deadlines and compliance setbacks.

What's next

With the registration foundation unified across both product lines, Laborie is expanding Smarteeva's role in their regulatory operations:

- Extending registration tracking to additional markets as Laborie expands into new geographies through acquisition and organic growth

- Connecting registration data with post-market surveillance workflows — so that complaint trends and adverse events can inform registration decisions in real time
- Deploying AI-assisted regulatory intelligence to monitor regulatory changes across target markets and flag registration impacts automatically
- Expanding automated submission capabilities to cover additional country-specific formats and emerging regulatory frameworks

See how Laborie unified product registration across their entire portfolio.

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