# Case Study

Smarteeva streamlined product registration & tracking challenge for a global medical technology company.

## ABOUT MEDICAL DEVICE CUSTOMER

A global medical technology company required a streamlined digitized system for speedy product registration, product status, expiration date tracker, Country requirement group all together. The company manufactured both diagnostic and therapeutic products that made tracking the entire product portfolio in a single application a challenge for the customer along with cost and time maintenance.

## OPPORTUNITY

Managing product registration within a single cloud based system was a challenge and their previous registration software restricted product tracking submissions with regulatory authorities around the globe.

- Multiple spreadsheet systems with no cross-link to documentation and country requirement templates was unsustainable and time-consuming in the long run.
- Tracking individual product expiration dates without unified automation was complex and disrupted end-to-end process efficiency.
- Managing product registrations, licenses and regulatory impact assessments across the entire product portfolio in a single, global application was unthinkable.

## SOLUTION

Smarteeva's product registration system was implemented. The registration process, starting from product categorization, expiration date, registration, ready to use country wise template, submission management all were automated with Smarteeva. With dynamic dashboards and automated reports the regulatory affairs team had global visibility of their product portfolio.

- Utilizing our system, the medical technology company was able to improve data quality by reducing data duplicates and discrepancies.
- Smarteeva's unique product registration management system established a faster mechanism for faster response to health authorities with tracking features.
- Depending upon the type of submission (510(k), pre-market etc) made to the FDA, our system allows users to create, review, and send all related documents to the global authorities quickly.
- Smarteeva streamlined medtech company's complete control over submissions with real-time visibility into the progress of regulatory submissions through intuitive reports and dashboards.

## RESULT

### Unified Product Registration suite with Automation & Global alignment

- Introducing Smarteeva's automated Product Registration system made a notable difference in the way of handling product portfolio and global visibility. We simplified the end-to-end registration process by integrating the application with the company's ERP system. Thus saving time, resources and cost of manually categorizing product portfolio and each individual step of registration for the medical device company.
- Bringing ultimate value to our customers with expansion of our AI-enabled products remains our main focus that can help reform Post Market Surveillance and medical device reporting.