



Global Medical Device Company

**100,000 recall  
notifications.  
90,000  
customer  
responses.  
Spreadsheets  
couldn't handle  
it.**

**100K+**

NOTIFICATIONS  
TO CONSUMERS

**90K**

CUSTOMER  
FEEDBACK  
COLLECTED

**Global**

AFFILIATES &  
LANGUAGES

**ERP**

INTEGRATED  
RECALL  
LIFECYCLE

### About the customer

A leading global medical technology company that sells both large equipment (with trackable install bases) and smaller equipment distributed through third parties (where install base traceability was nearly impossible). The company needed a recall management system that could handle multiple simultaneous recalls across global affiliates, with letter translations, automated notifications, and structured feedback collection at a scale their spreadsheet-based process could never support.

## Challenge

The company ran recalls on spreadsheets. When a recall was initiated, the team manually identified affected customers, drafted notification letters, tracked which letters had been sent, waited for customer responses, and compiled feedback reports for regulators. At low volumes, this worked.

**At 100,000+ notifications, it broke.**

The problems compounded across three dimensions: scale, traceability, and global

Industry Global MedTech (Imaging / Diagnostics)

Pain point Spreadsheet-based recall tracking

Key outcome 100K+ notifications automated

Platform Salesforce + ERP integration

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

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complexity.

- **Spreadsheet-based tracking couldn't keep up with FDA requests.** The recall management process was entirely spreadsheet-driven. At the volumes the company handled, this was unsustainable. When the FDA asked for status updates on a recall, compiling the answer took days of manual data reconciliation across multiple files.
- **Install base traceability for distributor-sold products was nearly non-existent.** The company sold large equipment (directly, with trackable serial numbers and install locations) and smaller equipment (through distributors, where install base data was incomplete or missing). Figuring out which customers should receive recall notifications for distributor-sold products was guesswork. Data was scattered across multiple CRMs, and install base information from distributors was almost non-existent.
- **All recall letters needed translation and localization.** The company operated through global affiliates. Every recall letter had to be translated into the local language, adapted to local regulatory requirements, and approved before distribution. Managing this translation workload manually was slow, error-prone, and difficult to track.
- **No structured way to collect and track customer feedback.** After sending notifications, the company had no systematic way to collect customer responses, track acknowledgment rates, or compile feedback into reports for regulatory authorities. Responses arrived through various channels with no single point of consolidation.

*"We were sending 100,000 recall notifications and*

*tracking customer responses in spreadsheets. When the FDA asked for a status update, pulling the answer together took days."*

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## Approach

Smarteeva's approach was to replace the spreadsheet-based recall process with an automated, end-to-end system that connected the company's install base data, notification workflow, translation management, and feedback collection in one governed platform.

- **Connect install base data from every source.** Large equipment install bases from the company's own records, distributor-sold equipment data from partner CRMs, and ERP product data all needed to flow into one system. When a recall was initiated, the platform would automatically identify every affected device and every customer who needed notification.
  - **Automate the full notification lifecycle.** From letter generation through translation, distribution, and feedback collection. The quality team shouldn't be managing recall logistics in email threads and spreadsheets.
  - **Built-in regulatory reporting.** When a regulator asks "how many customers have acknowledged this recall?", the answer should be available in seconds, not days. Country-specific reports (FSCA, C&R) should generate automatically.
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# Solution

Smarteeva implemented an automated recall management system that unified the company's entire recall lifecycle, from affected-device identification through customer notification, feedback collection, and regulatory reporting.

**1** **Install base management with device-level traceability.** Smarteeva's install base system tracks the exact location of every affected device. For large equipment with serial numbers, this was straightforward. For smaller equipment sold through distributors, Smarteeva built a mechanism to trace device locations by matching distributor data, sales records, and customer registrations. When a recall is initiated, every affected consumer is identified automatically.

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**2** **Decision tree for statistically-driven feedback forms.** Smarteeva's decision tree collects data and generates specific feedback forms within minutes. Each form is statistically driven and tracks response percentages. The quality team sees completion rates in real time rather than waiting for manual compilation at the end of a recall cycle.

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**3** **Automated multi-channel notification.** Smarteeva's communication features notify all relevant stakeholders about recalls — customers, retailers, distributors, and regulatory bodies. 100,000+ notifications sent through the platform, with delivery tracking and follow-up automation for non-respondents.

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**4** **Automated letter translation and localization.** Smarteeva's translation technology lets the company initiate

letter translation and localization directly from the platform. All features are customized with localization and usability in mind — user interface, manuals, and language — to meet each target market's requirements.

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#### Customer feedback collection at scale.

90,000 customer feedback responses collected through the platform. Each response is linked to the specific recall, device, and notification, creating a complete audit trail from notification sent to response received.

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#### Country-specific regulatory reporting (FSCA and C&R). Smarteeva

automatically generates and sends reports to country-specific regulatory authorities. Field Safety Corrective Action (FSCA) notices and Corrective & Removal (C&R) reports are produced in the correct format for each jurisdiction, ready for submission.

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#### ERP integration for unified recall

lifecycle. The platform integrates with the company's ERP system, connecting product data, manufacturing records, and distribution information with the recall workflow. This removed the manual effort of registering product information and generating individual recall records.

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## Results

**The spreadsheet-based recall process is gone.** The company now manages the full recall lifecycle — from device identification through customer notification, feedback

collection, and regulatory reporting — in one automated platform.

- **100,000+ notifications sent through one platform.** Recall notifications that were previously compiled and tracked manually now go out through Smarteeva's automated system, with delivery tracking and follow-up automation built in.
- **90,000 customer feedback responses collected.** Every response is linked to the specific recall, device, and notification. No more consolidating feedback from email, phone, and paper responses into a spreadsheet.
- **Install base traceability for both direct and distributor-sold equipment.** The company can now identify every affected device regardless of sales channel. Distributor-sold products that were previously untraceable now have device-level recall coverage.
- **FDA and global regulatory status available in seconds.** When regulators ask for a recall status update, the answer is in the dashboard. No more days of manual data reconciliation across spreadsheets.
- **Automated translation and localization.** Recall letters are translated, localized, and approved within the platform. The manual translation workflow that previously delayed every global recall is replaced with an automated pipeline.
- **FSCA and C&R reports generated automatically.** Country-specific regulatory reports are produced in the correct format for each jurisdiction — ready for submission without manual formatting.

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## What's next

With the recall management foundation automated and processing at scale, the company is expanding Smarteeva across their post-market surveillance operation:

- Connecting recall data with complaint management workflows — so that complaint trends can trigger proactive field actions before regulators require them
- Expanding install base traceability to additional product lines and distribution channels
- Deploying AI-assisted recall risk scoring to prioritize device populations by severity and exposure
- Integrating with MedTechRecalls.com for two-sided recall communication between the manufacturer and health systems receiving the devices

## Still tracking recalls in spreadsheets?

See how Smarteeva automates the full recall lifecycle — from device identification through notification, feedback, and regulatory reporting.

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