Bioventus

Three systems. One replacement. Zero login required to file a complaint.

3 → 1
SYSTEMS CONSOLIDATED

0
LOGINS REQUIRED TO FILE

Minutes
MDR CREATED TO FDA SUBMITTED

AI
EMBEDDED ACROSS WORKFLOW

About Bioventus

Bioventus is a global leader in orthobiologics and active healing solutions — developing products that help the body's natural ability to heal. As their product portfolio and market reach expanded, the gap between their quality management tooling and their compliance obligations grew wider. Three disconnected systems, manual processes, and no AI capabilities left their quality team spending more time fighting software than managing quality.

Industry	Orthobiologics / Active Healing
Pain point	3 disconnected QMS systems
Key outcome	Unified complaint platform

Challenge

Bioventus was running three separate software systems to manage one complaint lifecycle. Complaints came in through one tool. Investigations happened in another. Regulatory reporting required a third. None of them talked to each other.

The result was exactly what you'd expect: **manual re-entry at every handoff, data inconsistencies between systems, and a quality team that spent more time navigating software than making quality decisions.**

Platform	Salesforce-native

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

Email address

Download case study ↓

- Non-scalable, on-premise technology. The previous QMS was manual, on-premise, and not designed for the pace or volume of a growing MedTech company. Every system update risked downstream issues.
- Multiple steps to do anything. The complaint lifecycle required navigating through layers of screens and manual processes. What should have taken minutes took significantly longer — and the complexity increased the chance of errors.
- No visibility into what changed. Tracking and analyzing information changes across the complaint lifecycle was difficult. The user community struggled to understand what had been modified and how those changes should inform regulatory decisions.
- CRM cases as a workaround. The team had been using standard CRM cases to manually file complaints — an approach that was neither cost-effective nor scalable, and offered none of the governance or audit trail a regulated process demands.
- External users locked out. Distributors, field teams, and customers who needed to file complaints had no way to do so without a Salesforce license — adding cost and friction to the most critical intake channel.

> *"We needed one system that could handle the full complaint lifecycle — intake to regulatory submission — without requiring every external user to have a license or our team to re-enter data three times."*

Approach

Smarteeva's approach started with a fundamental question: why was the complaint lifecycle spread across three systems in the first place?

The answer was common across the MedTech industry — the company had grown, added tools incrementally as needs arose, and ended up with a patchwork of systems that each solved one piece of the problem without connecting to the others. No single vendor had offered a unified solution that covered intake through regulatory submission, worked on Salesforce, and didn't require every complainant to have a login.

Smarteeva's approach centered on three principles:

- Replace, don't patch. Rather than integrating three broken systems, replace all three with one platform that handles the entire complaint lifecycle natively — from the moment a complaint is filed through investigation, reportability, MDR submission, and closure.
- Open the front door. External users — distributors, customers, field representatives — needed to file complaints without a Salesforce account. The system needed a public-facing, no-login intake channel that fed directly into the governed workflow.
- Embed AI where it reduces burden. Bioventus didn't need AI for the sake of innovation. They needed it to reduce the manual work that was slowing their team down — auto-completing forms, flagging missing information, surfacing similar complaints, and automating reportability decisions.

Solution

Smarteeva replaced all three of Bioventus's disconnected systems with one integrated complaint management platform on Salesforce — covering the entire post-market surveillance workflow with AI embedded at every step.

1. **No-login complaint submission URL.** Smarteeva launched a dedicated, public-facing URL where anyone — distributors, field teams, customers — can file a complaint without a Salesforce account. One click, no login, no license cost. The form captures all required information and feeds directly into the governed complaint workflow.

2. **AI-powered form auto-completion.** Smarteeva's large language model reads the information submitted through the URL and auto-completes the internal complaint form — extracting product details, event descriptions, and reporter information from unstructured text. The quality team reviews AI-populated fields instead of re-entering data manually.

3. **Unlimited file uploads.** Unlike the previous CRM workaround, which limited file sizes and attachment volumes, Smarteeva allows external users to upload as many large files as needed — photos, device logs, supporting documents — directly through the complaint URL. All attachments link automatically to the complaint record.

4. **Automated MDR reporting.** The full MDR reporting process is automated. An MDR can be created, completed, and submitted to the FDA within minutes — not days. Decision trees handle reportability logic automatically, routing

each complaint to the correct regulatory pathway based on jurisdiction.

5 AI-backed decision trees with proactive alerts. Decision trees powered by AI guide the reportability assessment. If any required information is missing, the system sends proactive notifications directly to the user's inbox — no need to check the system manually to discover gaps.

6 Similar complaints tool. Smarteeva's AI-driven similar complaints feature lets investigators locate and review records with shared issues, products, or event patterns — accelerating investigation and promoting consistent decision-making across the team.

7 User-friendly audit trail. Every feature — including the audit trail — is designed for the people who actually use it. The interface lets Bioventus's quality team quickly identify what changed, when, who made the change, and the before/after values — without digging through layers of legacy UI.

Results

The transformation was structural, not incremental. **Three disconnected systems became one.** The manual workarounds disappeared. The complaint lifecycle that previously required navigating between tools, re-entering data, and reconciling records now runs in a single governed workflow.

- 3 systems → 1 platform. Complaints, investigations, and regulatory reporting

consolidated into a single Salesforce-native application. No more system-hopping. No more data reconciliation.

- Zero-login complaint filing. External users file complaints from anywhere, anytime, with one click — no Salesforce license required. The cost savings from eliminating per-user licenses for external complainants alone justified the transition.
- MDR submission in minutes. Automated reportability decisions and pre-populated regulatory reports mean MDRs move from creation to FDA submission in minutes, not days.
- AI reducing manual burden. LLM-powered form completion, proactive missing-information alerts, and similar complaint matching give Bioventus's quality team hours back every week — time redirected from data entry to quality decisions.
- Audit-ready by default. Every complaint, investigation, and regulatory submission carries a complete audit trail from day one — designed to be read and understood, not just stored.

What's next

With the complaint management foundation unified and running on one platform, Bioventus is expanding Smarteeva across their post-market surveillance operation:

- Expanding AI capabilities through Smarteeva Orchestra — building custom agents for complaint triage, IMDRF code suggestion, and investigation pre-population
- Extending automated regulatory reporting to additional global markets beyond FDA

- Deploying real-time analytics and signal detection across the consolidated complaint data — identifying product trends that were previously invisible across three separate systems
- Rolling out the no-login complaint URL to additional product lines and distribution channels

Smarteeva's mission is to continuously deliver value by advancing our AI-enabled product suite — reforming how MedTech companies manage post-market surveillance and medical device reporting, regardless of where they are in their digital transformation journey.

Running complaints across multiple disconnected systems?

See how Smarteeva consolidates your entire post-market workflow in one platform. 30 minutes. Your use cases.

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