Dexcom

How Dexcom manages 3 million complaints a year on one platform

3M	300K	165M	250K
ANNUAL COMPLAINTS	MDRS PROCESSED	AUDIT TRAIL ENTRIES	DAILY MESSAGES

About the customer

Dexcom is a global MedTech company and one of the largest manufacturers of continuous glucose monitoring (CGM) systems. Their devices are used by millions of patients daily for real-time glucose tracking, generating complaint volumes that most quality management systems were never designed to handle.

Industry	CGM / Diabetes Technology
Pain point	High-volume complaint scalability
Scale	3M+ complaints / year
Platform	Salesforce-native

Challenge

Dexcom's previous quality management system was built for a different era. At the time of deployment, it handled complaint volumes adequately. But as the installed base grew — millions of patients using their glucose monitoring devices daily — complaint volumes grew with it. **3 million annual complaints. Over 300,000 MDRs. 165 million audit trail entries.**

The existing system couldn't keep up. Not because it was poorly built, but because it was never designed for this scale.

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

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- **25 process steps** to move a single complaint through its lifecycle — from intake to closure. Each step required manual intervention or handoff.
- **Extensive customizations** had made the previous system untouchable. Any update risked downstream issues and application outages. The system that was supposed to reduce risk had become a risk itself.
- **No scalable path forward.** With over 300,000 MDRs and a user community that needed fast, responsive tools, the system was bottlenecking the team instead of enabling them.
- **Regulatory tracking was opaque.** The user community faced difficulty understanding what information had changed and how those changes should inform regulatory decisions.

> *"The system needed to be fast and responsive even with 3 million annual complaints and 165 million audit trail entries. It also needed to be simple enough that the team could focus on quality decisions — not on fighting the software."*

Approach

Smarteeva understood that the challenge wasn't just complaint volume — it was the entire architecture of how post-market surveillance data was managed, reported, and acted upon. A comprehensive approach was needed, not a patch.

The engagement started with a full assessment of the complaint lifecycle: every handoff, every manual step, every point where data was re-entered or decisions were delayed. The 25-step process was mapped end-to-end, and Smarteeva identified where automation, governed workflows, and connected data could eliminate bottlenecks without sacrificing compliance or traceability.

Key design decisions:

- Scalability as a non-negotiable. The platform needed to handle 3 million complaints with no noticeable loss in system responsiveness — not today, but as volumes continued to grow.
- Usability over customization. Instead of building an endlessly customized system that would become untouchable (again), Smarteeva built configurable workflows that Dexcom's own team could adjust without vendor dependency.
- Audit trail as a first-class feature. With 165 million entries and growing, the audit trail couldn't be an afterthought. It needed to be designed so users could quickly understand what changed, who changed it, and what it meant for their regulatory obligations.

Solution

Smarteeva implemented an end-to-end complaints and adverse events management system on Salesforce — designed from the ground up for the kind of volume that breaks traditional quality management platforms.

1. **Scalable with zero performance loss.** 3 million annual complaints processed without noticeable slowdown. The system remains fast and responsive at 165 million audit trail entries — and continues to scale as volume grows.

2. **Usability-first design.** Every feature — including the audit trail — is built with the end user in mind. The team can see exactly what information they need, when they need it, without navigating through layers of legacy UI.

3. **Automated MDR reporting.** The entire MDR reporting process is automated. An MDR can be created, completed, and submitted directly to the FDA within minutes — not days. Decision trees handle reportability logic automatically for the US, EU, and multiple other jurisdictions.

4. **250,000 daily message integration.** Scalable integration with customer service applications handles a quarter-million daily messages — connecting complaint intake directly to the quality workflow without manual re-entry or system-hopping.

5. **Configurable, not customized.** Workflows, decision trees, and automation rules are configured through the standard Salesforce platform. Dexcom's admin team makes changes in clicks — no vendor engagement, no professional services, no risk of "untouchable" customizations.

What's next

With the complaint management foundation in place and handling 3 million+ complaints at scale, Dexcom is expanding Smarteeva across their post-market surveillance operation:

- Expanding AI-assisted complaint triage and classification to reduce manual review time as volumes continue to grow
- Deploying Smarteeva Orchestra for custom AI agent workflows — automating complaint field extraction, IMDRF code suggestions, and adverse event detection from complaint narratives
- Extending automated regulatory reporting to additional global markets beyond US and EU
- Building real-time product health dashboards powered by connected complaint, investigation, and adverse event data

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 scale.

See how Smarteeva powers complaint management at Dexcom scale.

30 minutes. Your use cases. Your workflows. Real product, not a slideshow.

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