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How Welldoc Built a **Five-Team Complaint Management System** with Automated FDA and Health Canada Submissions on Smarteeva

Welldoc develops BlueStar, an FDA-cleared prescription digital therapeutics platform for people living with diabetes. As a software-as-a-medical-device (SaMD) company operating across the US and Canada, Welldoc needed a post-market surveillance system that matched the complexity of its regulatory environment without requiring a large compliance team. Smarteeva delivered a single platform where Quality, Regulatory, Customer Care, Product, and Risk teams all operate inside one connected workflow.

5TEAMS ON
ONE PLATFORM**3**REGULATORY
SUBMISSIONS
(MDR, MIR, CVR)**FDA**NEXTGEN API
DIRECT SUBMISSION**Zero**MANUAL STEPS FOR
NON-REPORTABLE
EVENTS

THE CHALLENGE

A SaMD Company with Multi-Market Regulatory Obligations and No Room for Manual Processes

Welldoc's BlueStar platform is an FDA-cleared, CE-marked digital therapeutic used by patients with type 2 diabetes. The product operates as a software-as-a-medical-device, which means every complaint, adverse event, and field report carries regulatory reporting obligations across the US (FDA) and Canada (Health Canada).

Before Smarteeva, Welldoc's complaint handling required coordination across multiple teams with no shared system. Quality, Regulatory, Customer Care, Product, and Risk teams each needed different access levels and different views of the same complaint data. Regulatory submissions were manual. Decision trees for reportability were not standardized. Audit trails were fragmented across tools.

THE IMPLEMENTATION

Five Teams, One Platform, Role-Based Access from Day One

Smarteeva deployed a role-based complaint management system where each team has precisely the access they need. No more, no less. Every team works inside the same record, but sees and edits only what their role requires.

QUALITY TEAM

Full Complaint Lifecycle Ownership

Complete access to create, edit, and close complaints. Manages investigations, triggers approval workflows, and handles complaint reopening. Read-only access to regulatory records ensures visibility without risk of accidental edits.

REGULATORY TEAM

Decision Trees + Submission Authority

Exclusive permission to create MDR, MIR, and CVR decision trees. Manages reportability assessment, regulatory record population, and direct submission to FDA (NextGen API) and Health Canada. Full edit access to all regulatory objects.

CUSTOMER CARE TEAM

Complaint Intake + Approval Participation

Creates support cases that flow into complaints. Participates in the multi-level approval workflow. Can submit complaints for approval and track resolution status. No access to regulatory decision-making.

PRODUCT TEAM

Complaint Visibility for Product Intelligence

View access to complaints, investigations, and product registration data. Uses complaint patterns to inform product development and software update prioritization. No edit access to quality or regulatory records.

RISK TEAM

Targeted Risk Assessment Fields Only

Access limited to five risk fields on the complaint record: severity, risk ID, risk assessment, and two additional risk parameters. Can view all complaint data but cannot modify anything outside the risk assessment section. This separation ensures risk scoring stays independent of complaint investigation.

What Smarteeva Built for Welldoc

Automated Decision Trees with Conditional Logic

Two conditions auto-execute decision trees without manual input. When the country of incident is the US and the product is not manufactured by Welldoc, the system creates a decision tree and answers "not manufactured by Welldoc" automatically. When the country is the US and severity is no harm, negligible, or minor, a second decision tree fires with a "not reportable" decision. Zero manual steps for non-reportable events.

Direct FDA MDR Submission via NextGen API

MDRs are submitted directly to the FDA through the NextGen API. The system tracks acknowledgments through three stages (ACK-1, ACK-2, ACK-3). An automated batch job runs every 20 minutes to process submissions and fetch acknowledgments. For urgent submissions, a manual "Submit to FDA" button allows immediate filing with real-time ACK retrieval. If ACK-3 fails, the MDR automatically returns to Open status for correction.

MIR Submission to Health Canada (4-Status Flow)

MIR records follow a four-status workflow: Opened, Pending Approval, Approved, Submitted. A "Check Form" validation identifies missing mandatory fields before submission. After approval, regulatory users confirm pass/fail status. On pass, the MIR moves to Submitted. On fail, it returns to Open and the full process restarts. CVR records follow a similar flow with auto-populated fields from product registration.

Auto-Population from Product Registration

When a complaint generates regulatory records (MDR, MIR, CVR), Smarteeva auto-populates fields from the linked product registration, including manufacturer details, device information, and regulatory classification. Account and contact data flows through automatically. Regulatory users fill only patient information and submission-specific fields. This eliminates manual re-entry across regulatory forms.

Smart Audit Trail on Every Object

Every field change across every object is tracked with timestamps, old values, new values, and the user who made the change. Color-coded visual indicators show insertions, updates, and deletions at a glance. Audit trail is activated on support cases, complaints, investigations, MDRs, MIRs, CVRs, and all related objects. Meets 21 CFR Part 11 requirements for electronic record traceability.

Multi-Level Approval with Complaint Reopen

Complaints move through a two-level approval workflow. The system blocks closure until all child records (investigations, MDRs, MIRs, CVRs) are closed. If any child record is still open, the complaint stays at "Investigation Complete" and cannot advance to "Pending Approval." Rejected approvals return the complaint to its previous status. A dedicated reopen button allows closed complaints to be reopened with a mandatory reason, restarting the investigation workflow.

WHAT CHANGED

From Fragmented Tools to One Connected System

5 → 1

Teams consolidated
onto one platform

Auto

FDA submission via
NextGen API + ACK tracking

Zero

Manual data re-entry
across regulatory forms

100%

Field-level audit trail
on every object

Before Smarteeva vs. After

Regulatory submissions: Manual assembly from fragmented sources → Auto-populated from product registration with direct API submission to FDA and Health Canada.

Reportability decisions: Unstandardized, person-dependent → Automated decision trees that fire on conditions (country + product, country + severity) with zero manual input for non-reportable events.

Team coordination: Five teams using different tools and views → One platform with role-based access where Quality, Regulatory, Customer Care, Product, and Risk all work inside the same complaint record.

Audit trail: Fragmented across tools → Every field change on every object tracked with timestamps, old/new values, and user attribution. 21 CFR Part 11 compliant.

Complaint closure: Manual status tracking → System blocks closure until all child records (investigations, MDRs, MIRs, CVRs) are closed. Multi-level approval with mandatory reopen reason if reopened.

What Smarteeva Delivered for Welldoc

Welldoc needed a post-market surveillance system that could handle the regulatory complexity of a SaMD product distributed across the US and Canada, without requiring five different tools for five different teams.

Smarteeva delivered one platform where Quality owns the complaint lifecycle, Regulatory controls decision trees and submissions, Customer Care handles intake, Product gets visibility for development decisions, and Risk scores complaints independently. Every regulatory submission (MDR, MIR, CVR) auto-populates from product registration data. Decision trees fire automatically when conditions are met. FDA submissions go through the NextGen API with acknowledgment tracking. Every change across every record is audit-trailed.

The result is a connected system where complaints move from intake to regulatory submission to closure without manual handoffs, without data re-entry, and without the risk of a missed filing.

What Sets This Implementation Apart

5-Team Role Architecture

Each team sees and edits only what their role requires

Auto Decision Trees

Conditional logic fires without manual input

FDA NextGen API

Direct submission with 3-stage ACK tracking

Health Canada MIR

4-status flow with pass/fail validation

About Welldoc

Welldoc is a digital health company focused on chronic condition management. Its flagship product, BlueStar, is an FDA-cleared prescription digital therapeutics platform for people living with type 2 diabetes. BlueStar provides AI-driven, personalized real-time guidance integrated into clinical workflows. Welldoc is headquartered in Columbia, Maryland. welldoc.com

See Smarteeva In Your Workflow

30 minutes. Your use cases, your data, your regulatory markets. A live walkthrough configured for your team.

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