smarteeva

Case Study

Smarteeva solves High Volume Complaints handling challenges for a Medical Device company

ABOUT MEDICAL DEVICE CUSTOMER

One of the largest manufacturers and producers of glucose monitoring systems required an overarching system for Post-Market surveillance and effective Complaint management system. Even though the business had a top quality complaint management system in the market, the ever changing business landscape, product and technology updates without increasing scalability was difficult to achieve.

3M
Annual Complaints

300,000
MDR's

165M
Audit Trail Entries

250,000
Daily Messages

OPPORTUNITY

Managing large complaint volumes with efficiency and scalability was a challenge, and their previous quality management system could not handle the unique challenges:

- The previous Quality Management System was not scalable to the unique needs of a high volume Complaint Handling Process. With over 3 million annual complaints and over 300,000 MDRs, the user community needed the system to be fast and responsive.
- Extensive customizations made previous QMS untouchable. Any update would cause downstream issues and application outages.
- The previous QMS System was difficult to use, and it took-25 process steps to go through the complaint lifecycle.
- The user community faced difficulty tracking what information had changed and how analyzing these changes could help them make informed regulatory decisions.

SOLUTION

Smarteeva understood the unique business requirements of Post-Market surveillance and complaint management systems by figuring-out that a comprehensive post market surveillance duty lies beyond receiving and reporting complaints to regulatory authorities. Smarteeva implemented an automated system with compliance and dependability in mind.

- Smarteeva is scalable with no noticeable loss in system responsiveness even after 3 million annual complaints and over 165 million Audit Trail entries.
- All of Smarteeva's features are designed with usability in mind, even Audit Trail has a unique UI to help users understand quickly what information they need to focus on.
- Smarteeva completely automated the MDR reporting process. An MDR can be created, completed, and sent to FDA within minutes.
- Smarteeva completely automated the decision trees and regulatory reports for the EU and multiple other countries.
- Smarteeva's scalable integration with customer service applications allows exchange of over 250,000 daily messages.

RESULT

Unified Complaint management systems with cost-savings

- Since introducing Smarteeva's Complaint Management System, the difference has been notable. It has resulted in simplifying the complaints management process by introducing a user-friendly interface that lets the user detect the "useful" information without investing much time and resources. Thus, saving costs and time for the medical device company.
- Bringing ultimate value to our customers with expansion of our AI-enabled products is our main focus that can help reform CMS and medical device reporting.