Case Study

Smarteeva replaced an unscalable Quality Management System used for Complaints handling for a Medical Device company

ABOUT MEDICAL DEVICE CUSTOMER

One of the leading manufactures of diagnostic products for cancer, cardiac health, infectious diseases, women's health and diabetes management required an overarching system for effective Complaint management system and post-market surveillance. Even though the business used a leading complaint management system in the market, the dynamic business landscape, product and technology updates without increasing scalability was difficult to achieve.

500K
Annual Complaints

16K
MDR's

42M
Audit Trail Entries

200K
Inquiries

OPPORTUNITY

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

- The previous Quality Management System (QMS) was not scalable to the unique needs of a high-volume Complaint Handling Process. With over 500K annual complaints, 200K Inquiries and over 16K 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 more 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 200K annual complaints and over 42 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's scalable integration with customer service applications allows exchange of over 10K daily messages.
- Using Smarteeva's AI suite (Smart Intelligence) like
  - Automated Decision Trees, for assessing reportability in the US, EU and all other countries
  - Smart Decisions, for automated risk assessments and initial complaint analysis
  - Similar Complaints, for easy viewing and finding of records with similar issues and products.
  - Quick review of similar records with user controlled ability to copy data from Similar Complaints
  - Smart Templates, for quickly and easily applying template data into a record
  - Smart Notification, for personalized email notification

RESULT

Scalable 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.