› Solution Brief

Business Impact

The Medical Device Reporting (MDR) regulation (21 CFR 803) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA.

US Food and Drug Administration

Challenges

- Efficiently accessing, processing and analyzing volumes of customer-reported medical device quality and safety information from all relevant data sources.
- Significant costs created by suboptimal business processes, leading to reduced profitability and potential fines and reputation damage.
- Rapid visibility into trends in customer complaint data across all global market product and safety reports to identify emerging quality or safety issues quickly and save product recall and litigation costs.

Improve Medical Device Quality and Safety Through Post-Market Surveillance

Each year, medical device manufacturers may receive several hundred thousand medical device adverse events or product complaint reports. In the US, the FDA outlines the reporting requirements of medical device manufacturers, importers and user facilities for all device-related adverse events and product complaints. And noncompliance may cost millions in fines every day for failing to report certain adverse events and product problems within deadlines. These fines decrease profitability and may prompt additional regulatory scrutiny.

Effective post-market surveillance is critical to monitor device performance and detect potential safety issues caused by the use of a medical device. Increased visibility into trends in customer report data can help identify emerging quality or safety issues more quickly and save significant product recall and litigation costs.

Our Approach

SAS provides advanced analytics, visualization and reporting for post-market surveillance that help medical device companies ensure that the medical devices supplied to patients are efficacious and safe. We provide software and services to help you:

- **Integrate and score adverse events and product complaints automatically** from internal and external data sources such as product complaints, adverse event reports, regulatory reports, product reliability reports and device safety databases – even unstructured data. Scoring algorithms can separate significant issues from those that don't affect patient safety.
- **Analyze product complaints and adverse events**. Increase speed and reduce millions of dollars spent on post-market surveillance processes by automatically coding and prioritizing complaints. SAS® quickly identifies and prioritizes significant medical device events for further investigation and possible mandatory reporting as required by the FDA and Canadian, European and international regulations related to medical device manufacturers. Content categorization uses advanced linguistic technologies to automatically apply your company's business rules to extract insights from text data in real time on a high volume of customer-reported issues.
- **Monitor and visually report on product complaint trends**. SAS offers visualization and reporting to more rapidly identify device performance trends across the globe. With web-based exploratory analysis, analytical expertise is not a requirement for using predictive analytics to gain precise insights into product complaint trends. Uncover common characteristics and clustering among complaints that might indicate a problem at a specific manufacturing facility. SAS also provides the ability to visualize data across several product complaint channels, including using the FDA's MAUDE database.

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THE POWER TO KNOW®

The SAS® Difference:

Real-time access to complete quality and safety data, complaints and adverse events

By putting your trust in SAS, your company can gain greater consistency in decision making through improved product complaint trending and global reporting from post-market surveillance – thus lowering costs and strengthening regulatory compliance.

- For over three decades, SAS has been used to integrate and analyze quality and safety data from a wide variety of data sources – a required component of successful medical device post-market surveillance.
- Using SAS can significantly reduce your costs of monitoring the quality and safety of your medical devices. As the market leader in advanced analytics, SAS is uniquely positioned to limit regulatory risk and lower costs through the automated application of your own business rules without custom programming.
- SAS provides both advanced analytics and easy-to-use visual analytics to fully integrate and streamline your customer complaint processes. Using SAS, you don't have to integrate point solutions from multiple vendors.
- SAS provides the added benefit of wider access to medical and business users for analyzing complaints and trends. This facilitates improved decisions about product safety and quality concerns in addition to ensuring a faster response to emerging issues and events.

Providing visual analytics and reporting to identify trends in quality or safety issues more quickly, SAS saves your company significant manufacturing, product recall and litigation costs – in addition to preserving your company's reputation with patients and health care providers.

Case Study:

A leading medical device company

Situation

A leading medical device company had a manual, inaccurate and costly process to evaluate thousands of customer problems that resulted in multiple regulatory fines for late reporting. The company also lacked comprehensive global reporting and visibility into global trends in product complaint data.

Solution

SAS provided the ability to virtually eliminate manual processing by automatically coding and prioritizing global product complaints according the company's business rules. The SAS solution quickly identifies high-priority issues for rapid review to lower the risk of regulatory fines. SAS also provided the ability to identify trends and visualize information across several product complaint channels. The company can now use the power of SAS predictive analytics to model reports from all sources, including the MAUDE database.

Results

Using SAS, the company lowered costs and increased accuracy and efficiency by:

- Identifying millions of dollars in direct savings from automating the manual coding process.
- Significantly lowering its risk of regulatory fines as it can now focus on significant adverse events and product problems more quickly.
- Improving processes for product complaint trending, root cause analysis, and exploratory quality and safety surveillance.

What if you could …

Automatically categorize and process all relevant quality and safety information?

Virtually eliminate medical device regulatory reporting fines through automatic processing of the vast quantity of reported issues?

Easily visualize product complaint trends to identify emerging issues more quickly?

You can. SAS gives you THE POWER TO KNOW®.

SAS Facts

- SAS is the gold standard for the analysis and reporting of clinical trial data.
- For more than three decades, pharmaceutical and medical device companies have trusted SAS to derive greater insight from information.
- Today, SAS has customers at more than 75,000 sites in 138 countries worldwide.

Learn more about SAS software and services for life sciences at: sas.com/lifesciences.

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