smarteeva

TRANSFORMING MEDICAL DEVICE POST MARKET SURVEILLANCE

THE SMARTEEVA SOLUTION

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Introduction

In the last decade, the medical device industry has faced increasing challenges in managing complaints and post-market surveillance. A staggering 20% annual increase in medical device complaints over the past 12 years has underscored the complexity and burden of handling these issues. The rise in medical device usage, coupled with stricter government regulations and heightened public awareness, has made the complaint management process arduous for companies. Sales and service personnel, often the first to hear of any product issues, express frustration over the obligation to report every complaint or adverse event. This situation is further compounded by the fact that complaint management is a primary focus during audits and is heavily scrutinized by regulatory agencies worldwide.

Moreover, the industry has witnessed a 42% average annual increase in recalls over the past five years, adding to the already substantial reporting obligations of companies. High-profile cases, such as the Philips CPAP machine recall, have spotlighted the intense scrutiny complaints receive, leading to significant consequences for manufacturers. This increased focus is not isolated to specific types of devices, as seen with hip/knee replacements and textured breast implants, which have driven the push for more stringent reporting requirements in the EU under the EU MDR regulations.

The Smarteeva Initiative

Recognizing these challenges, Smarteeva was founded with the vision to revolutionize Post Market Surveillance in the medical device sector. Our aim was to transcend the traditional approach of mere data entry and form-filling. We envisioned Smarteeva as an integral part of our clients' teams, not just a tool but a partner capable of guiding and even assuming complete control of post-market surveillance activities. Our mission is to mitigate risks for device companies and transform their perception and execution of post-market surveillance processes, thereby enhancing product quality, company reputation, competitive edge, and customer satisfaction.

42%

average annual increase in recalls over the past five years

Transforming Complaint Handling and Post Market Surveillance

The current landscape of complaint handling and post-market surveillance is marked by a reliance on manual data recording and processing, with a narrow focus on compliance. This approach has come at a significant cost to productivity. Additionally, the annual 20% increase in complaints and Medical Device Reports (MDRs), along with the proliferation of international regulations, further exacerbates the challenges faced by the industry.

Post-market surveillance teams often find themselves mired in basic data collection tasks, with little time allocated to essential activities such as risk assessment, product improvement, and enhancing patient safety. The integration of risk management into complaint-handling systems is notably lacking, due to organizational silos and the limitations of current Quality Management Systems (QMS) or Complaint Handling Systems, which do not incorporate risk management features.

Moreover, the diffusion of complaint-handling processes throughout organizations is minimal, with a significant gap in self-service capabilities for both third parties and device users. This lack of self-service options represents a missed opportunity for improving productivity.

20%

Annual Increase in Complaints

The Smarteeva Solution

Smarteeva is designed to address these challenges head-on, offering a suite of features that revolutionize the handling of complaints and adverse events. Our platform lowers risks, enhances customer satisfaction and engagement, and ultimately boosts sales while accelerating product market entry. Key features include:

Integrated Risk Management

Seamlessly incorporating risk management into the complaint handling process.

Smart Complaint Templates

Automating data entry and facilitating rapid complaint resolution.

Similar Record Functionality

Identifying and leveraging data from similar cases to improve efficiency.

Automated Regulatory Reporting

Streamlining the creation of MDRs, MIRs, CVRs, and regulatory reports like PSURs.

Integrated Data Lake with AI Functionality

Enabling natural language searches and providing insightful answers to complex queries.

Conclusion

Smarteeva stands at the forefront of transforming Post Market Surveillance for the medical device industry. By automating processes, integrating risk management, and enhancing productivity through self-service capabilities, Smarteeva not only aims to mitigate risks but also to elevate the standard of post-market surveillance. Our commitment is to empower medical device companies to improve product quality, boost customer satisfaction, and achieve competitive advantage, all while navigating the complex landscape of global regulations and increasing complaint volumes. Smarteeva is not just a solution; it's a revolution in post-market surveillance.