Fact Sheet

Integrated Solutions to Drive Proactive Post-Market Surveillance

Maximize Patient Safety with Recall Management and Prevention

The medical device vigilance process requires you to collect, analyze and report adverse events and product malfunctions. It can be challenging to know what is reportable and by when you need to notify the regulatory bodies. This is particularly true as the volume of adverse events communicated via social media, real-world evidence and other proactive sources grows in significance.

Historically, post-market surveillance (PMS) has been reactive due in part to limited technology and reduced regulatory requirements. It has relied on manually collating and reporting adverse events, such as device malfunctions or patient injuries, and trending complaints which can trigger field corrective actions, leading to recalls. However, with an increase in data availability, PMS approaches will need to be more predictive, leading to earlier detection of potential product failures in the field.

IQVIA™ MedTech has the experience, vision and technologies to support manufacturers and identify the most relevant PMS solutions for their organization.

Capture and investigate customer complaints and report adverse events to the relevant regulatory bodies.

Develop, augment or remediate your quality system with assistance from MedTech industry experts.

Manage MedTech field corrective actions and product recalls with comprehensive processes and real-time reporting.

Report and analyze QMS data from all stages of the product lifecycle to reduce downstream quality issues and recalls.

Moving from Reactive to Preventive

Regulatory authorities are starting to emphasize the importance of PMS plans that are based on proactive data gathering and analysis. This need often becomes amplified when you're faced with a product recall or with findings from regulatory authorities and notified bodies. In those instances, it may be too little, too late, accelerating the effort to comply, which can become prohibitively expensive and may require additional resources, experience, or expertise. To meet these challenges, you need access to:

- **People** who understand the changing post-market regulatory landscape and scalable resources required for recall-related activities
- **Regulatory technology and consulting experts** that can support diverse global reporting requirements and improve product traceability
- **Processes and systems** that are efficient, flexible and scalable
- **Cloud-based solutions** for leveraged flexibility and real-time reporting capabilities
- **Technology** that can support the needs of complex global business
- **Analytics** that can feed proactive approaches to inform post-market activities

Integrated Recall, Remediation and Quality Compliance Solutions

Whether you're trying to better understand and report on adverse events, facing a product recall or FDA enforcement, or you wish to develop a more proactive approach to these activities, IQVIA MedTech can help. We offer product monitoring, consulting and recall management support services to mitigate risk, minimize business disruption and ensure quality compliance within the changing regulatory landscape.

Capture

- Complaint Case Handling including FDA eMDR Submissions
- Outsourced Case Management
- Managed Services Complaint Tracking, Trending and Metrics
- Global Vigilance Evaluation and Submission
- Post-market Surveillance
- Interim Complaint and Vigilance Support
- Adverse Events Tracker

Advise

- Reviewing complaints for global reportability
- Supporting the recall decision through CAPA HRA & HHE processes
- Managing and deploying field actions
- Developing and submitting 21 CFR Part 806, EU FSCA and ROW reporting forms as on-site interim support for manufacturers
- Developing proactive PMS systems to reduce recalls

Recall

- FDA recall, correction and removal support
- Integrated, software and service-based solution to manage product recalls and field corrective actions, including:
  - » Notifications
  - » Acknowledgment reconciliation
  - » Call Center
  - » Field Deployment
  - » Product Returns & RGAs
  - » Warehousing
  - » Destruction
  - » Reporting
- Real-time activity tracking to simplify and expedite meeting reporting requirements
- Real-time visibility into the tangible, financial impact of a recall

Prevent

- Remediation services
  - » Post-enforcement
  - » Re-inspection
  - » Preparation
  - » Mock Inspections
- Best Practice Quality Management Solutions (QMS) for:
  - » Nonconformance and CAPA management
  - » Complaint Case Handling
  - » Quality Audits
  - » Change Control
  - » Incoming Inspection
  - » Supplier Quality Management
  - » Document Control
  - » Training Management
  - » Proactive Quality Intelligence and Analytics

IQVIA™ MedTech, part of IQVIA (NYSE:IQV), is dedicated to supporting the needs of the medical device and in vitro diagnostics industry, focusing on the orchestration of "concept-to-market" business processes to improve patient care. IQVIA MedTech Solutions are powered by the IQVIA CORE™, delivering unique and actionable insights and execution capabilities at the intersection of extensive domain expertise, transformative technology, unparalleled data and large-scale analytics. IQVIA is a leading global provider of information, innovative technology solutions, and contract research services.

IQVIA MEDTECH

CONTACT US
meddevice@iqvia.com
iqviamedtech.com