Postmarket Surveillance Including Complaint Handling and Vigilance Reporting

RQMIS has a team dedicated to helping companies with complaint handling, serious event reporting, and complete postmarket surveillance.

Regulatory bodies across the globe impose regulations and guidelines for manufacturers and their postmarket surveillance programs, including complaint handling and reporting serious injuries/deaths (e.g., Medical Device Reports, Vigilance Report). However, many companies haven't invested enough in their quality staff, systems, processes, procedures, training, and management to ensure quality postmarket practices. Some companies may have had an unexpected increase in postmarket data as the result of new product introductions or product changes, and thus have inadequate resources to respond.

With better recognition of the value of postmarket data and with proper support and resources, a medical products company can better protect patients and respond more quickly to quality issues while complying with regulatory bodies. According to a review of the FDA 483 database, warning letters related to Product Complaint handling are the second most frequently cited observation. These observations are most frequently issued due to lack of or inadequate procedures, failure to follow established procedures, and lack of documented evidence (good documentation and data integrity). As part of a company's postmarket surveillance activities, a complete complaint handling program consists of maintaining records of complaints and serious injuries/deaths for predictive analytics which help reduce device recalls, minimize disruption of patient support, improve outcomes, and reduce operational costs.

These services include:

- Complaint Handling
- Adverse Event Reporting
- Quality Metrics and Trend Analysis
- CAPA (including recalls 21CFR806/810)
- Health Hazard Analysis
- Post Market Clinical Follow-up Studies/Registries
- EU Post-Market Surveillance Plan Compliance

All the above processes will comply with local regulatory requirements to assure compliance with, but not limited to:

- Medical Device GMPs – 21CFR820
- MDR – 21CFR803
- ISO13485
- ISO14971
- EU MDR/IVDRR
- MDR for the UK
- Health Canada

RQMIS INC.

110 Haverhill Road, Suite 524 | Amesbury, MA 01913 |USA | +1 978-358-7307
4 Whitan Way | Witney OX28 6FF |Oxfordshire, England | United Kingdom | +44 20 84 34 7731
Ave. Diagonal 409 1st Floor | Barcelona 08008 | Spain | European Union | +34 936 26 86 70

www.rqmis.com

Classifying Postmarket Feedback

Proper classification of postmarket feedback is critical. On average, complaints can cost an additional $404 apiece compared to general feedback and non-complaints. On the other hand, if you don't categorize something as a complaint when you should, it can lead to consequences from regulatory authorities including warning letters.

What are the steps to properly manage complaint feedback*?

*We have identified in bold those steps we routinely help clients manage efficiently and effectively

1. ***Complaint is received via email, phone conversation, voicemail, or post.***
2. ***Complaint is recorded by complaint handler/tech support (designated person).***
3. ***An initial complaint record is created, and the complaint is recorded in the Complaint Log.***
4. ***Complaint is reviewed by RA/QA or designee to decide if MDR/Vigilance Report is needed for a serious adverse event (if yes, follow *MDR reporting procedure/process; if no, continue with the complaint process).***
5. ***Contact customer/consumer who filed the complaint to gain details about the complaint and circumstances leading up to the complaint. Request return of complaint device for evaluation, or photos of complaint items.***
6. Determine best course of action for correcting complaint (exchange, return, engage customer directly by advising them via phone call or email exchange directing them on how to resolve the complaint issue).
7. ***Perform complaint investigation (if product is returned) and reviewing all documents associated with the manufacturing of that product/lot, such as batch records, calibration records, quality records, etc.***
8. Perform complaint investigation of personnel, interview those directly involved with the production on the device.
9. Perform evaluation of returned product/parts or pictures, determine if complaint is repeatable and/or recognized.
10. ***Complete complaint report compiled with all information obtained.***

After the cumulative receipt of complaints and the results of the investigations, a company must perform the following 3 steps:

1. Perform trend analysis
2. Perform risk analysis and trend complaints compared to sales figures of faulty device
3. Determine if CAPA is required and if yes, initiate CAPA request

RQMIS has the expertise to perform/support all three of these tasks

MDR Reporting Procedure

Medical device companies must decide if each complaint involves serious injury or death or a malfunction that could have caused a serious injury or death.

To handle a serious injury or death report, the typical process consists of the steps below. RQMIS can complete and submit these reports on behalf your company.

1. Complete and submit an authorization form allowing us to complete a serious injury/death report on our client's behalf.
2. Populate specific fields as required in the FDA's MDR portal and create the vigilance report for the EU Market.
3. Upload corresponding photos and documents associated with the adverse event.
4. Review report internally for completion.
5. Send report to client for review, comments, and signature.
6. Upload packet to the FDA portal and create the vigilance report packet.
7. Acknowledge receipt of packet by FDA/EU and communicate acknowledgment to client.

With the adverse event packet submitted, RQMIS can act as the company's quality representative and handle all communication with regulatory bodies.

- Our team members have backgrounds in biomedical, medical, and clinical studies in the US, UK, EU, and Canadian markets and can evaluate and report serious injuries/deaths in those jurisdictions.
- We can assist in proper feedback classification and any notification of regulatory bodies.
- We can monitor packet evaluations and develop any additional documentation that may be required.
- We can complete adverse event reports in a timely manner.
- We can assure consistency in adverse event reporting.

MDRs are public records. With that in mind, RQMIS will perform all tasks with complete confidentiality using language that keeps your best face forward, and which is written in the most accurate and consistent, but least self-deprecating way.

PMSS provides input to many other parts of your quality system

PMS data plays a key role in product related documentation that is required by regulation. RQMIS are experts at integrating the latest PMS data within these other documents. Examples include:

- **Clinical Evaluation Reports:** Documents the conclusions of a clinical evaluation of your medical device which consists of analyzed clinical data that was collected either from a clinical investigation of your device or the results of other studies on substantially equivalent devices. These reports require review and consideration of PMS data.
- **Risk Management Procedures:** The identification, understanding, control, and prevention of risks. Once a product is released to the market, a company must monitor postmarket use of their product and feed PMSS data back into the risk assessment of the product to determine if any new risks are evident or if any original risks are occurring at a higher frequency than anticipated. In either case, further analysis can determine if further action needs to be taken with product or labeling.
- **Labeling Requirements:** Labeling for a product must reflect the latest feedback from the PMSS via the risk management process.
- **Postmarket Surveillance Reports:** The requirement that manufacturers monitor and report on their medical device performance postmarket.
- **Technical Documentation:** Technical documentation supporting CE marking requires ongoing review and consideration of PMS data to assure continued compliance with the EU MDR/IVDRR.

There are many ways to fulfill the multifaceted requirements needed to create and complete your Postmarket Surveillance program. Let RQMIS guide your team through this laborious process and create a working system that grows with your company and helps your company thrive in this ever-competitive medical device market.