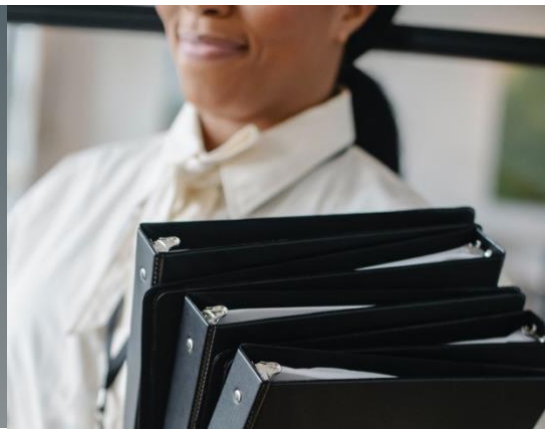
Postmarket Surveillance Service (PMSS)



Based on the positive feedback from our clients, RQMIS has identified an opportunity to introduce a comprehensive and unique Post-Market Surveillance Service (PMSS) for medical device companies.

This service will allow us to help structure and support a client's post-market surveillance program, including their complaint handling processes. Our goal is to help complete and trend complaints, which will help with product upgrades and improvements, as well as increase client satisfaction. RQMIS will help to Identify, complete, and submit Adverse Event Reports to satisfy regulations.

The PMSS will have major services that will enable our clients to get a much better understanding of how well their products are performing in the field and capture opportunities for improvement.

CASE STUDY

Complaint Handling Backlog Project

The Situation:
The North American Division of a Japanese medical device manufacturer approached RQMIS with the need for support in addressing observations identified in an FDA Warning Letter regarding Complaint Handling, including the timely investigation and closing of complaints. Specifically, they had a backlog of 10,000+ complaints that had to be processed, investigated, and closed.

The Solution:
RQMIS and another consultancy were asked to work on the complaint backlog project for an initial 6-week trial period to determine which company would be awarded the full contract. RQMIS won the full contract over our competition due to the volume of complaints resolved which greatly exceeded our competitors, as well as our organization of tasks, and our very low error rate.

Many regulated manufacturers find themselves without the resources or processes to efficiently manage post market data. The challenge begins with the processing of feedback from the field and determining how to manage this communication, in particular communications that are product complaints. Companies have the following challenges when managing complaints.

When the resulting backlog isn't cleared quickly and completely, the issue can compound into serious safety and compliance problems requiring many hours of work to resolve. With a backlog of customer complaints that are continually ignored, customer service satisfaction declines.

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

Companies have the following challenges when managing complaints:

- Distinguishing between feedback, repairs, and complaints
- Managing the volume of complaints (either because of volume of complaints and/or lack of resources)
- Complaint processing is not standardized or inadequate
- Trend analysis is limited or not standardized
- Inadequate linkage to risk management activities (e.g., FMEA)
- Understanding when a CAPA is necessary (including recalls)
- Timely decision of reporting serious adverse events

Post-Market Surveillance truly is an essential component of customer service and business success. Not only is it the means to gather valuable customer insight, but it also helps a company's progress to improvements that lead to reduced costs, increased profitability, and increased customer satisfaction.

In addition, when discovered by federal regulators, the first and most obvious consequence of a complaint backlog is a written observation. This could cite improper investigation, and in some cases, inadequate quality oversight.

Like any observation, expect this to trigger more digging. Regulators will likely examine your processes and the backlogged files themselves to determine what is causing the delay. Complaints indicating missed MDRs, or unknown patient risks will likely lead to critical observations and/or warning letters or other serious enforcement actions.

To address this opportunity RQMIS has designed a Post Market Surveillance Service (PMSS) to support clients in managing post market data with RQMIS support. A primary component of a PMSS is handling/investigating customer feedback/complaints and whether such feedback is reportable as a serious injury/death to the competent authorities, including FDA. To understand how we can support this process we have provided below the critical steps in complaint handling and serious injury/death reports.

We feel strongly that we have a solid team backed up by proprietary technology to provide the global market with our complaint handling and adverse event reporting services. To assist our clients and prospective clients, our services will include experts, who will analyze the clients' current post-market surveillance systems, and work to create a comprehensive strategy to customize an advanced filtering code which will improve the client's complaint handling workflow, and adverse event reporting processes.

Our Post-Market Surveillance service will create many benefits to our clients

- The ability to confidentially work with your complaint handling initiatives and to solve your complaints or Adverse events assuring the language used in the complaint is accurate and balanced
- Being vigilant about how we portray events
- Providing administrative overhead and regulatory expertise
- Quicker allocation of resources with a lower cost, as we can provide a trained worker that doesn't require startup time, health insurance or benefits from the Company
- Based on complaint analysis and trend analysis we will provide feedback to the risk management process (e.g., Updating Failure Modes and Effects Analysis)
- Much more effective trend analysis using empirically validated data
- Where we see trends, we will make sure they are entered into their CAPA program
- International regulatory expertise
- Ability to easily assist with other integrated RQMIS services quickly

RQMIS can help with any or all the following tasks associated with complaint closures and overall Post-Market Surveillance Programs:

- Create or update Complaint processing and adverse event reporting procedures
- Organize complaint files
- Create spreadsheets and filtering codes for tracking and trending complaints
- Perform metric and statistical evaluation on complaint trends
- Create and complete CAPA investigations when complaint trends are identified
- Complete root cause analysis, RPN determination, and investigational summaries for individual complaints that will pass Quality Audits
- Evaluate risk management documents (FMEA) to evaluate the stated risk assessment at time of device release, to assure the risks associated with complaints have not exceeded the stated risk evaluation.
- RQMIS can assist in setting up Phase 4 post market clinical studies.
- Provide on-site audits to help improve your complaint evaluation and investigation processes, and suggest improvements in this area and other quality, regulatory, and clinical processes as needed

How can we help with adverse event reporting?

- Our team members with backgrounds in biomedical, medical, and clinical studies in the US, UK, EU, and Canadian markets can evaluate and report adverse events in those jurisdictions.
- RQMIS will complete the adverse event reports in a timely manner
- RQMIS will assure consistency in adverse even reports being sent to EU, UK, US, and Canadian authorities.
- RQMIS will assist in proper classification and notification of regulatory bodies

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