APCER LIFE SCIENCES
Together for better health

CASE STUDY

Managing Seamless Transition and Establishing KPI-driven Operations

Therapeutic area: Cardiovascular

Product type: Drugs

Geography: US

Product life cycle stage: Post-approval

About the Client

The client is a leading innovative pharmaceutical company with products marketed and under development in key therapeutic areas such as oncology, immunology, and urology.

Business Challenge

The pharmaceutical company had been outsourcing its entire medical information (MI) operations to another service provider for several years. The company had limited in-house resources and faced the following challenges while managing the existing vendor:

- **Inefficient handling of volume spike:** The client's existing vendor was unable to provide customized support in the event of spikes and showed inefficiency in managing overall project work.
- **Lack of skilled resources:** The vendor did not deploy healthcare professionals, thus impacting the way product and medical inquiries were handled.
- **Lack of transparency:** There was no visibility of queries because of suboptimal reporting processes; escalation and deviation processes were inadequate.
- **Lack of quality:** Non-compliance to the service level agreements (SLAs) was noted, and the quality of deliverables did not meet the sponsor's expectations.

Overview-Outsourcing Medical Information services

Outsourcing MI services can be a major decision for pharmaceutical companies. A company decides to outsource when there are limited skilled resources in-house or the processes are inadequately managed and there are increased costs associated with managing critical tasks in-house. MI is the front-facing function, and the team plays a critical role in responding with empathy to product complaints and medical inquiries or collecting adverse events associated with the drug or device. These challenges include greater compliance risks stemming from heightened regulatory obligations, increased complexity of information, handling high volumes of inquiries, and changing communication channel preferences and expectations. The teams need to acquire a sponsor-specific approach in disseminating accurate information to the stakeholders. MI teams also act as a partner to other functions such as pharmacovigilance and the product quality department.

Sponsors, therefore, need a trusted partner who is expert in managing this critical, front-line function with ease and efficiency - a team who is scalable in situations of crisis and is able to respond to queries in an appropriate manner.

Solution

APCER Life Sciences was chosen as the service provider to transition the MI processes and implement an effective operations set-up. The scope of the services was not limited to handling and responding to MI queries. The team also managed the initial intake and follow-ups of adverse events, product quality complaints, and content development for the call scripts. APCER's Quality Assurance group performed a gap analysis from the existing processes, and the following enhancements were made to mitigate the shortcomings:

- **Resource allocation:** A dedicated project manager with a team of subject matter experts (all HCPs) were assigned to manage and guide this project with defined tasks and timelines. In addition to this primary team, other members of the MI team were also cross-trained on the client's products and processes, so that they can act as backup in case of volume spikes.
- **Aligning to scope of services:** Operations were scaled up to set up the MI database, validate the database, develop content, and implement the processes.
- **Comprehensive training effectiveness assessment:** The team was thoroughly trained in the client's processes and supported higher than expected volumes of inquiries with no escalations.

Outcome

The APCER team helped the client by:

- ensuring scalability of processes and resources to handle spikes in call volume,
- providing customized support for handling inquiries and streamlining the MI processes,
- working on process improvement and ongoing monitoring of key performance indicators (KPIs) in real time, and
- ensuring that each inquiry is handled with expertise and empathy.

APCER's Medical Information Capabilities

- Services delivered by trained and skilled **pharmacists/physicians with extensive experience**
- **24x7 contact center with multilingual support** (130+ languages with coverage in 30+ countries)
- **MI services** for drugs, biologics, and medical devices
- **Integrated** pharmacovigilance services
- **Contact center support for** Risk Evaluation and Mitigation Strategies **(REMS).**
- **End-to-end MI services,** including intake of and responding to medical inquiries, adverse events, and product complaints, and development and maintenance of standard and custom response letters
- **Training** of field force and medical science liaison (MSLs)
- Patient and HCP **engagement programs** and clinical trial support

APCER LIFE SCIENCES | Together for better health
Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2013, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 11 4650 0802

For Business enquiries, please email at: marketing@apcerls.com
For General enquiries, please email at: info@apcerls.com