APCER LIFE SCIENCES
Together for better health

CASE STUDY

End-to-end pharmacovigilance support for a UK-based pharmaceutical company

Therapeutic area: Multiple therapies

Product type: Drugs

Geography: UK, EU

Product life cycle stage: Post-marketing

About the Client

This client is an emerging pharmaceutical company which specializes in products for post-surgical pain and anesthesia with additional clinical pipeline assets in sedation, antibiotics, oncology and biosimilars. These products and assets are infusible pharmaceuticals that are cost-effective and known to provide safe and efficient alternatives to existing products approved in the US, UK and Europe.

Business Challenge

This pharmaceutical company had an in-house PV team but a limited understanding of the applicable regulations. It had two anesthetic medication products in the UK market (one marketed and other non- marketed). They had a requirement to setup an efficient 24x7 medical information contact center to handle queries from the United Kingdom and European countries such as France, Germany and Poland. The company had limited resources and required support for setting up an end-to-end compliant PV framework so that it could focus on their market expansion in European countries.

Overview - Unique PV Needs of Small Biopharma Companies

A robust pharmacovigilance (PV) system is a vital need for pharmaceutical companies intending to market their products across countries globally. Rising adverse drug reactions (ADRs) due to wide usage of medications, drug characteristics and the prevalence of concomitant diseases are key factors driving the need for outsourced PV systems. Small-to-mid-sized companies tend to have one or two drugs in clinical trials and a few others in the pipeline but no marketed products. While study CROs and in-house systems may work for initial studies, challenges arise when these small companies expand their products and undergo clinical trials in multiple countries. Also, when more products are added to the portfolio, they require the help a provider to process and report on the data. Another challenge is to address the dynamic changes to regulations. These companies may lack efficient in-house trained or experienced PV staff to write and report for complex cases as well as maintain a compliant PV system.

Solution

APCER Life Sciences was chosen as the preferred safety services provider by the company. We created a designated team, established processes, and executed on the project in a phase-wise manner. We completed onboarding within 3 months, which covered:

- configuration and hosting of two compliant databases: a safety database and a medical information database,
- established the medical information integrated response management system for receiving medical information queries for the United Kingdom and a gradual expansion of the same to other countries such as France, Germany and Poland,
- knowledge transfer and team training,
- completing the pharmacovigilance system master file (PSMF) update and EudraVigilance (EV) registration,
- database migration for legacy cases, and
- preparation of the signal detection and periodic safety update report (PSUR) schedule.

Following the set up of a compliant PV system, end-to-end adverse event support services were delivered for marketed product and for clinical trials as required per each country's regulations: individual case safety report (ICSR) (receipt triage, processing and submissions), aggregate reporting, qualified person responsible for pharmacovigilance (QPPV), Extended EudraVigilance Medicinal Product Dictionary (XEVMPD), 24x7 medical information, literature review, PSMF and signal detection.

Outcome

- Ensured compliance by assessing, initiating and managing end-to-end PV services amid a dynamic regulatory environment.
- Quick turnaround and cost-effective approach for managing active processes.
- Enabling effective, smooth transistion and process expansion in multiple territories for marketed authorized products.

Our Pharmacovigilance Capabilities

Domain Expertise: 100+ physicians, 90% healthcare professionals supporting drug safety and Pharmacovigilance.

Experience and expertise in different product types including Drugs, Vaccines, Biologics, Biosimilars, Cell and Gene Therapy products / Advanced Therapy Medicinal Products, Medical Devices, and Combination products.

Risk Management Expertise: Risk management solutions provided by our experts and QPPVs are core to our governance model and project oversight.

Efficient Project Management: Our unique "two-in-a-box model" deploys a Client Partner and Delivery Head to ensure timely execution on deliverables and inculcate strong governance to monitor compliance at each stage through the life of the project.

Proactive Approach: Service-level adherence (SLA) and quality deliverables, coupled with strategic alignment to provide business value, makes us a trusted partner for PV for this pharmaceutical company.

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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 27001:2022, 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) 79 6677 8600

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