APCER LIFE SCIENCES
Together for better health

CASE STUDY

Setting up agile PV operations for a US-based pharmaceutical company

Therapeutic area: Multiple therapies

Product type: Drugs

Geography: US, EU

Product life cycle stage: Post-marketing

About the Client

This client is a biotech pharmaceutical company which specializes in the development and commercialization of niche, complex fermentation and semi-synthetic biopharmaceutical products across multiple therapeutic areas. They manufacture over 30 products for immunosuppressant, oncology, antifungal and anti-bacterial indications.

Business Challenge

This biopharmaceutical company had a single immunosuppressant marketed product in the US. The company had limited understanding to set up their pharmacovigilance system and address regulatory requirements. They were seeking immediate support across all PV functions so that they could focus on their market expansion plans.

Overview - Pharmacovigilance Setup

A compliant pharmacovigilance (PV) system is vital for pharmaceutical companies intending to market their products globally. It is important that these companies abide by the local and global regulations where they intend to market their products. Meeting varied and sometimes complex regulatory demands is a challenge for pharmaceutical companies. It is especially difficult for small and medium sized companies to manage these safety requirements. The challenges faced by these companies includes the cost of setting up the PV system, lack of available skilled resources, and pressure to market their products given their limited resources in a competitive environment. Typically, small and medium sized companies rely on a specialized safety partner for their end-to-end clinical trials and PV system support. A competent and proactive safety partner can assimilate the necessary product knowledge and apply the necessary processes and services to ensure end-to-end compliance.

Solution

APCER Life Sciences, as their safety partner, initiated the PV setup in a phase-wise manner. A dedicated and highly skilled team was assigned to initiate and execute the project who:

- assessed the current system and implemented improvements to ensure audit-readiness,
- engaged a shared services team of experts and operators across PV functions (case processing, literature, signal management),
- worked on to setup a compliant safety database within 6 weeks,
- initiated knowledge transfer that included APCER training the customer's in-house team on basic PV and database usage, and
- supported them for complex activities such as REMS preparation and submission.

With the inception of the project, the cases were triaged, processed, and submitted per the regulatory requirements.

Outcome

- Set up of an efficient PV system for timely submission of cases.
- Set up of cost-effective and agile PV operations.
- On-demand advisory for compliance to dynamic regulatory changes.
- Enabling the company to focus on its market expansion objectives.

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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