APCER LIFE SCIENCES
Together for better health

CASE STUDY

Enabling global expansion by establishing an integrated PV system

Therapeutic area: All therapy areas

Product type: Drugs and devices

Geography: US

Product life cycle stage: All clinical trial phase through the post-approval lifecycle

About the Client

A global pharmaceutical company who is a brand leader of marketed Pharmaceutical and Nutraceutical products worldwide. They focus on developing innovative products for challenging health disorders.

Business Challenge

This company faced multiple issues in demonstrating an effective PV system to UK and European regulators. This resulted in a series of inspections from the MHRA which led to several critical findings, which included:

- Lack of aligned processes to support a global Pharmacovigilance (PV) system.
- Declining performance statistics which involved the build-up of a huge backlog of:
  - 4,000+ Individual Case Study Reports (ICSRs) with a compliance rate of 80%.
  - 600+ open Corrective Actions and Preventive Actions (CAPAs) which were critical in nature.

It is evident that there was a significant need to build a robust, compliant pharmacovigilance system.

Overview - Integrated Pharmacovigilance System

Any sponsor of clinical trials of investigational medicinal products must instigate arrangements for safety reporting as part of regulatory compliance. The responsibilities of the sponsor with respect to pharmacovigilance and safety reporting must be fullfilled by creating a diligent reporting system inclusive of education, training and oversight of the process. With the increasing volume of information about drugs and their adverse effects, there is an urgent need to develop a unified process. The parallel co-existence of clinical safety databases across studies and/or geographies creates confusion for pharma companies. There are additional efforts for reconciliation accompanied by inefficiencies, risks with regards to regulatory incompliance and cost. Therefore, a single integrated system, across all studies, for capturing safety information ensures data consistency and facilitates access to the data with streamlined signal detection.

Solution

APCER life sciences was chosen as a partner to help the global pharma company to set up and align the PV system to function smoothly with processes to enable consistency for the long term.

- **Collaborative Approach for Establishing a Global PV Governance Model**

  APCER with strong domain expertise in PV, collaborated with the client to identify innovative solutions by establishing a global PV governance model.

- **Set up an Integrated Single Safety Database**

  To support the governance model, an integrated single safety database was created, which enabled the reporting of cases to all major health authorities worldwide.

- **Implemented Harmonized Process**

  A standard, harmonized process was implemented across all the clinical teams oversight.

Outcome

- Timely submission of cases to regulatory authorities, due diligence, CAPA management processes enacted.
- Compliance rate rose from 80% to 98% for on-time submissions of ICSRs and 100% for aggregate and Risk Minimization Plan (RMP) submissions.
- Effective management of complications involved in the transition from another vendor to APCER at the centralized location.
- Post project transition, multiple regulatory inspections were conducted by major global health authorities such as the FDA, BfArM, MHRA, ANSM, TGA and Health Canada. All inspections were successful with no major findings.

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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