APCER LIFE SCIENCES
Together for better health

CASE STUDY

Established a unified, global PV system for a pharma company after multiple M&A

Therapeutic area: All therapy areas

Product type: Drugs and devices

Geography: US, EU, Australia, New Zealand, Asia Pacific

Product life cycle stage: Post-marketing

About the Client

This global pharmaceutical company is focused on serving the needs of patients and healthcare providers around the world by providing access to niche established medicines in more than 90 countries. They have a diversified portfolio of more than 200 patented and generic products.

Business Challenge

This global pharmaceutical company underwent multiple M&A events in a span of 5 years. The product portfolio, geographical locations and existing pharmacovigilance (PV) processes varied in each of these business integrations. Different PV vendors also provided services the companies acquired. One product acquired had authorizations in more than 100 countries and was transitioned to the new sponsor in a phased manner. The resultant goal of this company was to ensure compliance by having a single, unified global PV system in place both to maintain regulatory compliance and to minimize duplication of work. Timely completion of all the activities to achieve this goal was critical to ensure compliance.

Overview - Mergers and Acquisitions

Pharmaceutical, healthcare and life science companies are increasingly expanding into new markets for expansion of their product portfolio and revenue growth through mergers and acquisitions (M&A). M&A activities are common across the pharma industry, which has led to the following challenges:

- Lack of clarity on roles and responsibilities.
- Inconsistent processes and interfaces across legacy systems.
- Minimal product portfolio coordination and oversight.
- Poor integration of safety databases.
- Resistance to integration or harmonization
- Backlogs and inconsistencies of cases.

Companies therefore, are required to harmonize inconsistent processes and to design a unified operating model, integrate new processes and ensure smooth migration of data after a merger or acquisition.

Solution

APCER Life Sciences was the selected vendor to provide a unified, global PV system. The team at APCER performed a detailed gap analysis of the existing PV systems to be integrated. The following tactics included:

- A customized integration plan was drafted with actions and timelines for each of the integration of products & processes.
- A detailed job aid was preptared for the transitions performed in phased manner.
- Subsequently a data migration plan was drafted and execution of data migration related activities and validation were seamlessly executed. Data migrations for all the safety related data (ICSR, PSUR, signal, medical information etc. is performed and a single global database established.
- An efficient handover was performed to Qualified Person Responsible for Pharmacovigilance (QPPV) for European transitions to include all PV and related activities using predefined templates containing exhaustive list of activities to be transitioned.
- Resources were allocated as per the requirement and in due time, scalability was achieved.
- In addition, the data available from the signal process of the acquired company was evaluated and merged into the existing system.
- Detailed project plans, clearly defining roles and responsibilities, were aligned and drafted for the teams for follow-up during the transition phases and in the hyper care period post transition.

Outcome

- Regulatory compliance was ensured across multiple M&As.
- Significant gaps that were identified, accurately analyzed and fixed as per the process requirements.
- Scalability of team was seamlessly done and the process efficiency was done in less time.
- Customized support across different geographies, processes and products was provided to the client on real time basis.
- An effective and smooth expansion of processes to multiple geographic territories for marketing authorization was completed.

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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