APCER LIFE SCIENCES

CASE STUDY

Driving Global Pharmacovigilance Audit Compliance for a Global Pharmaceutical Leader

Therapeutic area: Multiple therapeutic areas

Product type: Drug

Geography: Asia, Europe, and the Middle East

Product life cycle stage: Postmarketing

About the Client

A leading global pharmaceutical organisation headquartered in the Netherlands, with a wide therapeutic portfolio spanning anaesthetics, psychiatry, urology, paediatrics, and infectious diseases, sought support for its PV audit programme and to ensure global compliance. The company operates widely across the Benelux Union and broader European markets and supplies products globally through partners, serving the European and other international territories.

Business Challenge

- Non-compliance with regulatory requirements for periodic PV audits of partners and vendors
- Lack of a robust, risk-based audit framework and limited QA resources
- Need for a sustainable global audit programme to meet regulatory standards

To bridge these gaps, the company's European Union (EU) Qualified Person for Pharmacovigilance (QPPV) approached APCER to design and implement a high-standard audit strategy. Based on APCER's rich experience and audit capabilities, the company engaged APCER to design and execute a comprehensive audit programme and to conduct PV audits.

Overview

Pharmacovigilance (PV) audits are a critical mechanism for ensuring regulatory compliance, patient safety, and the integrity of the PV system. Regulatory guidelines, including EMA-GVP (European Medicines Agency-Good Pharmacovigilance Practices) modules, ICH E2E (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Pharmacovigilance Planning), and the United States (US) Food and Drug Administration (FDA) PV regulations, mandate periodic and risk-based audits of the PV systems, business partners, affiliates, and service providers. These audits assess adherence to regulatory requirements, standard operating procedures (SOPs), compliance with adverse event reporting timelines, signal detection, risk management, and periodic reporting requirements. A structured, risk-based PV audit programme identifies high-risk areas and systems and helps schedule and plan the audit corresponding to the risk. Regular audits of the PV system, including the outsourced PV functions, vendors, and affiliates, ensure end-to-end oversight of the PV system, minimise the regulatory risks, and demonstrate robust governance to authorities. A comprehensive PV audit framework is therefore extremely important for organisations to achieve sustainable compliance, continuous quality assurance (QA), and regulatory confidence across global operations.

Solution

APCER's QA team, with rich expertise in global PV audits, provided end-to-end support through

Preliminary Assessment:
Gathering details of partners and affiliates

Risk-Based Planning:
Prioritising audits based on compliance risk and business criticality

Audit Execution:
Deploying experienced and qualified auditors to conduct rigorous evaluations of vendors, internal systems, and business partners

Our Quality Assurance Capabilities

Well-trained and experienced QA team, with domain experience of 500+ GVP audits within the QA team.

Experience in conducting audits in multiple regions, including the US, the EU, the United Kingdom (UK), and Asia, in various therapeutic areas over a wide range of products, including biologics.

Hands-on experience in end-to-end Quality Management System (QMS) services, e.g., Corrective Action and Preventive Action (CAPA), deviations, and SOP management by dedicated resources.

Actively supported and participated in over 100+ regulatory inspections, including the US FDA, the UK Medicines and Healthcare products Regulatory Agency (MHRA), and the EMA.

Outcome

Robust Audit Programme:
Implemented a structured and sustainable audit programme, achieved 100% compliance with the tactical audit plan, and strengthened its PV oversight of partners and affiliates.

Audit Achievements:
Successfully conducted 20 PV audits, including those of partners, affiliates, service providers, and system audits, within just 1.5 years of engagement. Additional audits are being planned based on risk assessment and the latest tactical audit plan.

Regulatory Compliance:
Achieved full adherence to the global PV audit requirements.

Appreciation from Client:
The client team, including the QPPV, provided excellent feedback on the proficiency of APCER's QA team, specifically noting the rigour of the audit conduct and reporting.

Long-Term Association:
APCER established a long-term strategic partnership with the client to manage and execute their global PV audit programme. What began as a targeted engagement for select audits has evolved into an enduring collaboration, underscoring the client's trust in APCER's exceptional delivery and audit quality.

Executive Summary

A leading global pharmaceutical company engaged APCER to design and implement a sustainable, risk-based PV audit programme to address the regulatory compliance gaps of non-conduct of PV audits. APCER conducted preliminary assessments, developed a risk-based audit programme, and executed comprehensive PV audits across business partners, affiliates, and service providers. This ensured adherence to global audit requirements, strengthened Marketing Authorisation Holder (MAH) governance, and established a structured and sustainable audit framework. APCER enabled the client to maintain global regulatory compliance, ultimately achieving operational excellence and enhanced oversight.

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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.

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