APCER LIFE SCIENCES
Together for better health

CASE STUDY

Ensuring Regulatory Compliance: Managing Global and Local Literature Surveillance for Drugs and Medical Devices for a Leading Pharmaceutical Company

Therapeutic area: Endocrinology, Critical care, Anti-infectives, Cardiovascular diseases and Pain management

Product type: Drugs and medical devices

Geography: USA, UK, EU and ROW

Product life cycle stage: Pre- and post-authorisation literature surveillance

About the Client

A leading speciality pharmaceutical company (hereinafter referred to as 'client') with a strategic focus on anti-infective, endocrinology and critical care medicines.

Business Challenge

The client found it difficult to efficiently monitor scientific literature to identify emerging safety concerns, adverse events and regulatory development relevant to their diverse product portfolio. Recognising the need for a proactive approach to pharmacovigilance, the client decided to implement a unified 'once and done' solution wherein a team of experts could perform both global and local literature surveillance activities. The client's challenges included:

- **Limited expertise, skills in literature surveillance** and lack of an adequate literature system.

Overview

Marketing authorisation holders (MAHs) are mandated to monitor the scientific literature of their products regularly to identify any new safety information, including adverse reactions. The monitoring involves both global and local literature searches. Global literature surveillance helps in identifying adverse reactions reported worldwide, ensuring comprehensive coverage, whereas local literature surveillance focuses on region-specific publications to capture any relevant safety data peculiar to that area. The information gathered from these searches is crucial for reporting adverse reactions to health authorities as part of pharmacovigilance activities. MAHs use these data to update product labelling, communicate safety information to healthcare professionals and patients, and ensure the safe and effective use of their products. Periodic monitoring of scientific literature is essential to stay updated on the safety profile of their products and to comply with regulatory requirements.

- **Multiple languages:** Dealing with a wide range of languages in the EU and ROW regions.
- **Multiple product types and worldwide authorisations:** A comprehensive understanding of each product and its literature was vital, given the client's diverse portfolio from multiple MAH acquisitions, with authorizations in 100+ countries.
- **Need for a quality review:** A robust quality control review process and optimised validation measures.

Solution

APCER developed a strategic approach to address the challenges:

- **Initiation with ~200 active molecules for global literature search:** A thorough analysis of client's portfolio to identify the scope of work and resources required, along with establishing clear communication channels for aligning with and understanding project's objectives.
- **Creation and implementation of a robust search string:** Use of a tailored robust search string, with search criteria refined, along with close collaboration between APCER and the client, to capture relevant data for the molecules, which provided optimal results.
- **Establishment of local literature services:** Tailored and comprehensive surveillance for each market's unique requirements, ensuring thorough and compliant monitoring of pharmaceutical literature globally.
- **Development of multilingual capabilities for different countries:** Translation of literature articles by certified translators, supporting the client's global presence.
- **Quality assurance measures:** Periodic validation measures and a two-round review process, with continuous monitoring and feedback to improve the accuracy and relevance of the data collected.
- **Team expansion:** Recruiting and training new members to accommodate supplementary active molecules for literature surveillance, to maintain efficiency and effectiveness.
- **Establishment and achievement of key performance indicators (KPIs):** Continuous review of the established KPIs with the client ensuring alignment and their achievement.

Outcome

- APCER's global and local literature surveillance system produced remarkable results and met the KPIs efficiently:
  - Successful monitoring of **~200,000 literature publications annually** with comprehensive coverage and timely identification of safety signals and regulatory updates.
  - **100% internal compliance** and an impressive **99.29% internal quality KPIs,** demonstrating high standards and accuracy in data collection and analysis.
- **Local literature search:** Services provided across five countries for **~95 active molecules** in house and in collaboration with local partners wherever required, **meeting all KPIs,** compliant with local regulations and requirements, with enhanced relevance and accuracy of surveillance efforts in each market.
- **Advisory services:** On-demand support to ensure compliance with regulatory changes, helping the client quickly adapt to evolving requirements.
- **Regulatory inspection readiness:** No major findings during planned inspections from key regulatory authorities, demonstrating the effectiveness of APCER's solutions and processes.
- **Operational efficiency:** Smooth, uninterrupted performance, showcasing APCER's consistent and reliable service delivery for client support.

APCER's Literature Surveillance capabilities

A dedicated team of healthcare professionals skilled in using literature search databases like Embase, PubMed, and customer-specific databases.

Proficient in conducting end-to-end literature searches and reviews, defining search strategies, and providing medical literature monitoring and local screening services per local regulations through an in-house expert team and strategic partners, along with procuring full-text articles.

Translation of literature articles by certified translators for high-quality multilingual capabilities in local literature surveillance.

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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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