CASE STUDY

Outsourcing pharmacovigilance activities to PharmaLex ensured full compliance and a successful MHRA PV inspection

Situation

A small company wished to outsource all pharmacovigilance activities. They were in the process of obtaining an EU marketing authorization and license approvals in other countries around the world for their product. As an applicant and future license holder they had to fulfil significant and complex pharmacovigilance obligations.

Challenge

There are many PV activities that must be fulfilled to ensure that legal obligations are met. In addition to ensuring compliance, PV has to comply with Good Vigilance Practice (GVP) and ensure that a product's benefit risk profile is continually monitored, thereby protecting patients' safety.

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Solution

Using our deep PV expertise and knowledge, PharmaLex ensured that the client met all its legal obligations, allowing it to market its product in the EU and other new territories. The PV obligations met included:

1. Provision of a qualified, EU-based Qualified Person for Pharmacovigilance (QPPV)
2. Case processing in accordance with mandatory timelines
3. Maintaining a global safety database
4. Monthly literature searching and signal detection
5. Continuous benefit risk evaluation
6. Periodic safety reports.

Benefits

The PharmaLex engagement delivered:

- Protection of the product asset, allowing the company to protect patients
- Support of sales worth €3m in Year 1
- Successful MHRA PV inspection with no critical findings

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