

BUSINESS CASE

Case Study Analysis: Helping a big company meet the expectations of the Authorities.



CHALLENGE

A leading global company focused on industrial gases, healthcare and engineering, with around 820 Marketing Authorizations for medicinal gases only in Europe, present globally in approximately 83 countries around the world.

The Client faced an inspection from the Swedish Agency (MPA).

- **34 findings** were found, **4** of them critical.
- The **EU-QPPV** lacked the **oversight** and **control** of the PV system.
- Company **lacked** an **adequate PV system** and **qualified personnel**.
- **Undefined PV training plan** for local vigilance officer.
- **Lack of experience** of **Deputy EU-QPPV**.



SOLUTION

The activities performed by Asphalion included:

- **Design** of a **robust** two-phase action plan.
- **Outsourcing** of **EU-QPPV** and **Deputy EU-QPPV** to Asphalion.
- **Fulfillment** of **pharmacovigilance requirements** according to regulations.
- **Asphalion PV QMS** system, **key** for the **development** of the client's **new PV QMS system**.
- Establishment of a **PV training plan**.
- **PSMF** update.
- **Implementation** of a **PV Database**, including validation, database configuration and migration.
- **Periodic activities management**: ICSR, global literature searches, EURD-List review, EV cases management, PSUR/RMP plan elaboration and submission, Eudravigilance, xEVMPD, social media screening, PV training, Signal detection, PSMF maintenance, and monitoring of European legislation.



OUTCOME

Successful collaboration:

- Rapid **closure** of all MPA **findings**.
- **Improvement** of **Global PV system** and of **local vigilance communication plan** and **network**.
- **Solid EU-QPPV oversight** of local activities in **EU** and **RoW**.
- **Consolidation** of **PV team**.
- **Compliant PV programme**.
- **Readiness** for **future inspections** by **regulatory authorities**.
- **Improvement** in subsequent audits and inspections **without critical findings**.
- **Oversight, control** and **transparency** of processes achieved.



Asphalion, key in the **setting up** of a **robust PV system**.