Pharmacovigilance Services

Choose the service you need

EU Regulations require each MAH to establish and maintain a PV System. Since 2006, we have been providing Pharmacovigilance services to Pharma Company. Our outsourcing proposals are highly customable to Clients' needs: from a global management of PV System to spot services

QPPV	Local QPPV
Eudravigilance	PSMF
Case processing	Literature screening
Signal Management	Risk Management
Safety Database	Third party management
QA & Auditing	PV Training

QPPV

"…the QPPV is an individual who is personally responsible for the safety of the human pharmaceutical products marketed by that company in the EU. "

A cost-effective solution: As GB Pharma, we have experienced resources that may act as QPPV on behalf of your Organization. to follow these tasks:

- Manage the PV System;
- Act as main point of contact for Cas, EMA and Inspection (24/7 availability)
- Oversee the safety profiles of your product portfolio;
- Continuously review and assess the benefit-risk balance
- Review and approve PASS;
- Manage Risk minimisation measures

OUR APPROACH AND FEATURES

- **An easy- and fast- customable PV System**
- **A cost-saving approach**
- **A Qualified and experienced staff**
- **A Global coverage**

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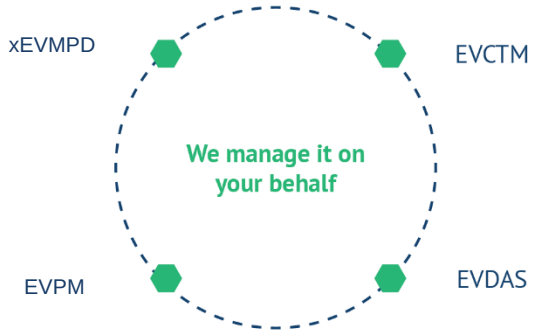
Local QPPV

According to local requirements and the Countries your product is authorized, you may need a local contact or responsible to be appointed We can provide such a person in each European Country and operating all local Pharmacovigilance activities.

EudraVigilance

"A centralised European database of suspected adverse reactions"



We can manage all aspects of Eudravigilance registration and maintenance, providing you qualified and trained users to manage all modules embedded within the European database.

PSMF

"…As legal requirements, each MAH should implement and maintain a detailed description of its PV System through a PSMF"

Our service incudes the drafting, the reviewing and general support for the PSMF Management. Our PSMF template is a dynamic document to be updated when changes impacting the PV System occurs.

Case processing

With an average 10.000 ICSRs, our solutions allow us to operate on your database by remotely entering and processing safety data or provide you with our validated Safety Database. All we do is to match your needs with the best cost-effective service.

Data Entry	**Quality Control**
Medical Evaluation	**ICSR Validation**
ICSR Submission	**Safety database**

OUR PLUS

An interactive online platform to share the PSMF with the MAH for periodically updating and ensuring timely exchange of information. Such a platform will be accessible to the key roles of the MAH who may interact and communicate with the QPPV

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Literature screening

Literature screening is active substance based. The most is the number of APIs screened by us the most is cost-saving proposal we do. For this reason, our procedures and systems allow us to be highly competitive on this service. We offer:

- a systematic **worldwide literature** screening service as part of your day-to-day drug safety operations. This is made through the medical screening of referenced database.
- **Local literature screening** of non-indexed journals. We have a comprehensive list of journals to be screened at local level.

Signal Management

"…A set of activities performed to determine whether there are new risks associated with an active substance or a medicinal product or whether known risks have changed"

We can support you in planning Signal Detection activities and undertake the cumulative review of safety data by analyzing the following sources:

- Line listing from Safety Database;
- Literature findings;
- Pre-clinical and clinical data;
- EVDAS;
- Competitor label information.

With an effective process and a medical team in place, we can support you with Signal Management with both spot or full services.

Risk Management

A Risk Management System for your product is a mandatory requirement. A Risk Management Plan (RMP) is required to be submitted as part of a new MA Application and risk minimisation measures (RMM) should apply, where applicable. At GB Pharma, our Risk Management experts may help you at drafting, reviewing and submit an RMP classifying important, identified and potential risks. Additionally, we help our Clients in establishing appropriate RMMs to maximise the use of your products and increase the safety of your products.

OUR PLUS

through our Clinical and Regulatory Department, we also help Clients in

- designing PASS, study registry, educational material and questionnaire
- to put into practice RMMs or to measure their effectiveness.

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Safety Database

Our Safety Database is installed on premises and is validated by following GAMP5 guidelines. Each client has its own specific site within the application where the ICSRs are managed with a specific workflow.
Our Safety Database is an Oracle® based software that ensure compliance with EMA and FDA regulatory requirements. All the ICSRs are tracked in the database to produce CIOMS, Line-Listings and Summary Tabulations to comply with PV activities as per regulation requirements, such as Signal Detection, data reconciliation and PV cumulative reports.

Third Party Management

Manage third Parties of your Organization, including commercial partners, vendors and providers is a key process of your PV System. Since the implementation of PV Technical and Safety Exchange Agreements, our support includes the compliance check and monitoring of your partners and the implementation risk assessment strategy.

QA & Auditing

Our Quality Assurance & Auditors experts have more than 20 years' experience in Pharmaceutical and CRO context. With a sound knowledge of GCP and GVP, we can support you in the following activities.

Auditing to third parties
Mock-up Inspection
Regulatory Inspection
Quality Manual
SOPs management
GxP Compliance

PV training

Initial and continuous training on Pharmacovgilance topics, as well as the safety of your products is an essential process that make your Organization able to collect safety information from any source.

We offer a flexible service made of face-to-face or remote solutions. We have an e-Learning Management System Platform that allow you to efficiently train medical sale representative or sale agents. Alternatively, our trainer experts may organize on-site training.

Contacts

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