

# How we manage your PV System

## We are not your provider

## We are your PV Department

EU Regulations require each MAH to establish and maintain a PV System.

Our experience begins in 2006, when we start to extend our business to Pharmacovigilance and Regulatory services.

Since that date we have experienced all regulations changes impacting Pharmacovigilance obligations and we have been managing Audits & Inspection on behalf of your Clients.

## — Strategic advice

Our PV System is built starting from a simple assumption: "***The Pharmacovigilance is a transversal matter of you Organization***".

Such an assumption allow us to manage your PV System efficiently and ensuring the highest level of compliance to GVP and applicable legislation.

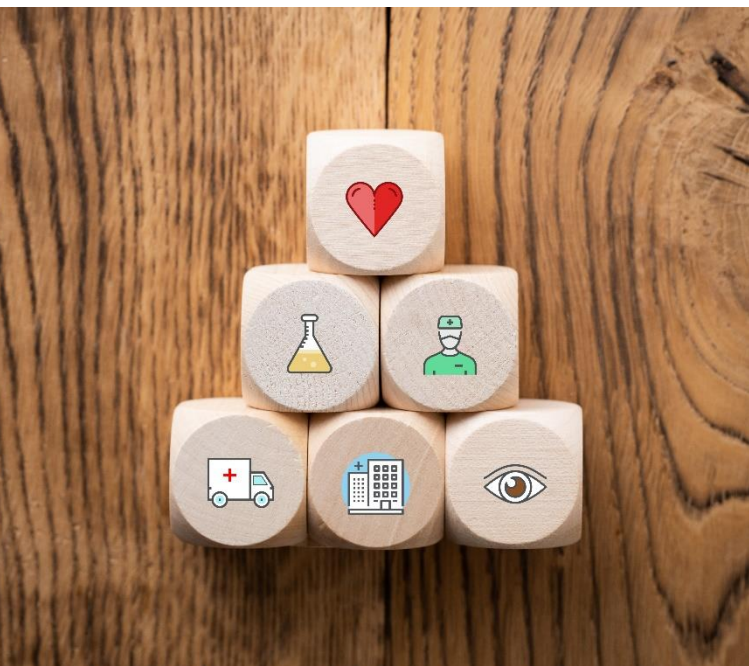
## — What we do

We make such processes easy, efficient and compliant to applicable regulation.

### The GB Pharma PV Quality system applied to you



procedures, processes, organisational structures, responsibilities, training, audit and controls



## — OUR PLUS

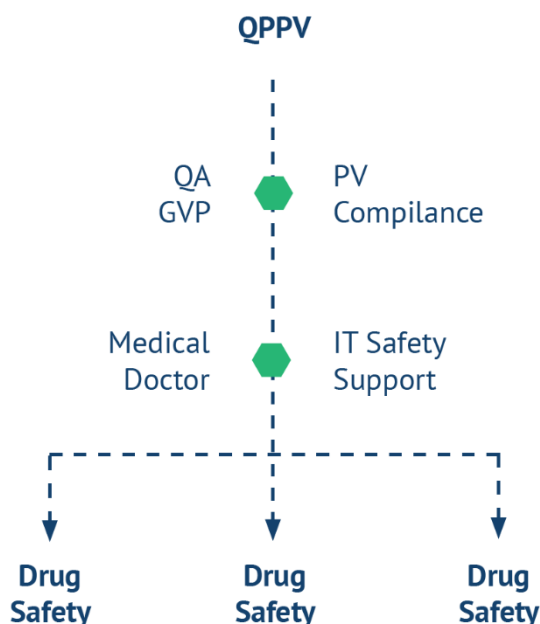
-  Proven experience
-  20 years experience
-  Flexible solutions
-  A global coverage

# How we manage your PV System

## — Our approach

Depending on the size and complexity of your Organization, we define a PV Cluster that will act as your Department of Pharmacovigilance and Safety matters.

Such a cluster may be composed by :



## — An Interactive PSMF platform

The Pharmacovigilance System Master File is the key documents to describe your PV System. In this regard, we continuously share it with the MAH for periodically updating and ensuring timely exchange of information. Such a platform is accessible to the key roles of the MAH who may interact and communicate with the QPPV.

## — Our plus

- A comprehensive set of technical procedures for technical aspects related to Pharmacovigilance;
- A set of easily customizable procedures to make Pharmacovigilance processes embedded within your Organization;
- An ISO-like PV Quality manual to link quality systems in term of Pharmacovigilance.

## — Contacts



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