

# Support for Start-up

## A feasibility assessment report to start a comprehensive support to partnership with us

Are you a Start-up planning to enter the European Union market or to expand your business within it? If so, we would be delighted to talk to and share with you the way we may support you. Our advisory and operational support encompasses a customizable package of services delivered by our multi-disciplinary team.

### — Strategic advice

Identify the best regulatory pathway to register your products within the EU. We provide advices to maximize the speed to market of your products and plan all the regulatory and legal aspects to ensure the highest level of compliance in respect to EU legislation. Our strategic advice together with our operational support allow you to efficiently and timely set-up your business within the EU.

### — Regulatory support

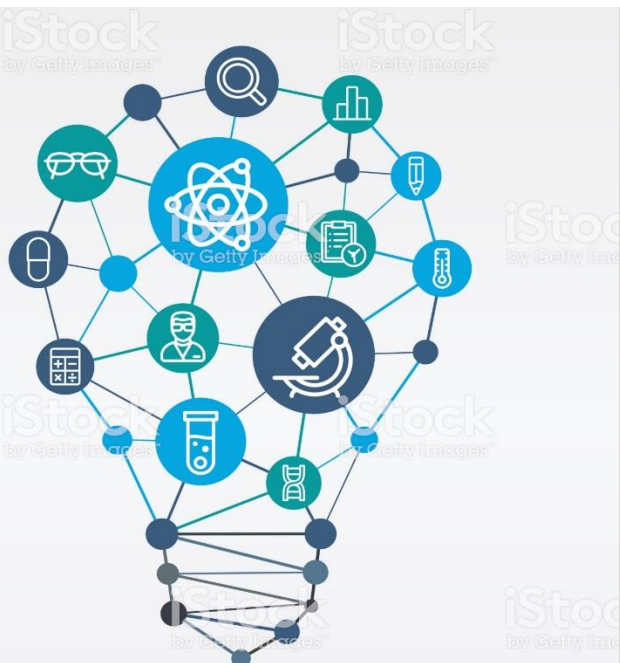
Manage all activities related to MA application and maintenance, assuring local regulatory requirements within the EU are met and speeding up time to market of your products.

### — Pricing & Reimbursement

Preparation of request for pricing (Price and Reimbursement Dossier), and operational support in submitting and negotiating it with Health Authorities. Through our Regulatory Intelligence we provide you advice on local requirements, timelines and procedures.

### — Power of attorney

Act on your behalf towards the EMA and national Competent Authority to manage regulatory procedures.

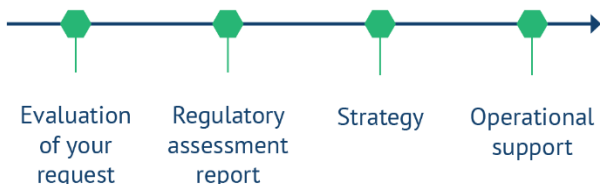


### — KEY SERVICES

-  Strategic advice
-  Regulatory support
-  Pricing & Reimbursement strategy
-  Power of attorney

## — How we manage it

The first step is to provide you with a **REGULATORY ASSESSMENT REPORT** answering to your questions and sharing with you our experts suggestions for a successful strategy.



Such an approach is the first step of a cooperation that may move on with a flexible approach targeted on your product portfolio and your Organization structure.

## GO FURTHER WITH OUR PARTNERSHIP MODEL SOLUTION

Our Partnership Model Solution begins from the idea to streamline the outsourcing model of our Clients. One vendor to satisfy your request and to take care of the life-cycle of your products within the EU.

## — Additional service for start-up

### Pharmacovigilance

Once your products are authorized, you will need to establish a PV System within the EU. Through our Pharmacovigilance Department we manage it on your behalf by providing the QPPV role and a customizable PV System.

### In- and out- licensing

Once your products are authorized, you will need to establish a PV System within the EU. Through our Pharmacovigilance Department we manage it on your behalf by providing the QPPV role and a customizable PV System.

” **ESTABLISHING A PARTNERSHIP WITH  
GB PHARMA MEANS THAT YOUR  
BUSINESS BECOMES OUR BUSINESS** ”

## — Contacts



Via Ferreri 11 – 27100 Pavia  
(Piazza Petrarca, vicolo tra Farmacia  
e Giardini Malaspina)



Tel: +39.0382.530059



Fax: +39.0382.302619



Mail: [info@gbpharma.it](mailto:info@gbpharma.it)

## — Area referent



### Chiara VINO

REG & PHV Coordinator  
[cvino@gbpharma.it](mailto:cvino@gbpharma.it)