Regulatory Affairs Pharmaceutical

Explore and manage Regulatory landscapes with us

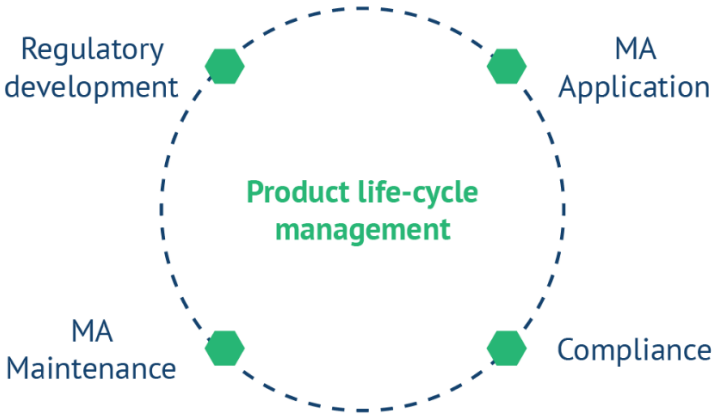
Our solutions are thought to be Client oriented and to make your product development run smoothly. Relying on your needs first, we do it through a pool of clinical and non-clinical regulatory experts supporting you in all phases of regulatory development.

…Manage 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.

Main services

Below is a list of key services we propose our Clients:

- MA applications;
- MA transfer;
- Variations and Renewals;
- Post-approval Life-cycle management;
- Due diligences;
- GMP Support;
- Technical writing (ASMF, CTD / eCTD)
- Risk Management;
- Regulatory harmonization and work-sharing procedures.



OUR PLUS

- **High Client retention**
- **Multi-disciplinary team**
- **Clinical and non-clinical expertise**
- **A Regulatory Intelligence Network**

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Local requirements compliance

Dealing with European and National procedures requires MAH to satisfy requirements at a regional level. We provide you with a Regulatory Intelligence network that help you to identify such requirements and implement a schedule work to achieve and maintain the highest level of compliance. Below is a list of processes impacted:

- Regulatory legislation;
- Pricing & Reimbursement;
- Scientific Service;
- Administrative aspects;
- Pharmacovigilance;

Risk Management

Through the synergy of a multidisciplinary team and combining pharmacovigilance, regulatory and clinical services, we support our Clients to promote safe use of medicines and safeguard health of patients by establishing an effective Risk Management System. Our experts can help you in identifying risks related to your products and define and measure the most appropriate RMMs.

GMP Support

Our support is delivered with Regulatory experts with a sound GMP background and cover the following topics:

- evaluation of suppliers of raw materials and finished products;
- audits to suppliers of raw materials and finished products;
- evaluation of production processes;
- evaluation of manufacturing documents;
- Support for quality issues.

Additional services

Through the synergy with our Clinical and Medical team, as well as a solid experience, we can support you in high specific topics, such as:

- Scientific advice
- Protocol Assistance
- Orphan Drug Designation (EMA, FDA)
- Pediatric Investigation Plan (PIP)
- Clinical Trial Applications

Contacts

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

Tel: +39.0382.530059

Fax: +39.0382.302619

Mail: info@gbpharmaservices.it