Global Regulatory Affairs: Expand your products worldwide

Successfully providing Registration Services since 2000

ASPHALION
Knowledge from experience

Global Submissions and Product Lifecycle Management

NCE I Biologics I ATMPs I Orphan Drugs I Generics I OTCs I Herbal Medicines

- Experience in **managing all types of EU, UK** and **US procedures**, as well as rollouts in RoW countries
- Subject matter experts **in direct contact with Regulatory agencies**
- **Submission** coordination, ensuring **compliance** with **critical timelines** and reducing **time to market.**

CP, DCP, MRP, RUP, NP	**IND, NDA, BLA, ANDA**	**60+ COUNTRIES**

ASPHALION
Knowledge from experience

One-stop shop

Support for the **expansion** of your product's portfolio:

- **Assessment** of **regional requirements**
- **Regulatory Strategy**
- **Network of reliable local partners** for global registration procedures
- **Support** and **management** of **new Marketing Authorization Applications** (compilation of documentation, submission, coordination and follow-up with authorities, etc.)
- **Management** of **variations** and **renewals**
- **Management** of **labelling,** including **multilingual packagings**

ASPHALION

Knowledge from experience

Looking to expand your portfolio around the world?

Worldwide Local experts

Regulatory intelligence

Time efficiency

Committed to your success

Dedicated
Subject Matter Experts

High Quality of deliverables