ASPHALION
Knowledge from experience

Drug Development Consulting Services

From Idea ➜ to Market

Partner with Asphalion's Drug Development and Scientific Writing experts to support **your product at every stage of development.**

What we offer

- **All product types**
  Generics, biologics, ATMPs, biosimilars, small molecules, new chemical entities
- **All indications**
  E.g., oncology, immunology, CNS, respiratory, rare diseases
- **Across all major regions and beyond**
  EMA, MHRA, FDA, NCA and RoW authorities
- **Flexible collaboration models**
  From single projects to continuous collaboration

Flexible and experienced, ready to adapt to your regulatory and scientific challenges.

ASPHALION
Knowledge from experience

Strategic support from day one

Helping you **navigate** and **analyze** scenarios to **make the right decisions:**

- Early-stage regulatory strategy and consultancy
- Regulatory roadmaps
- Feasibility assessments
- Gap analyses
- Bibliographic searches and preparation of literature justifications
- Ad hoc regulatory support

ASPHALION
Knowledge from experience

Key Pre-Marketing regulatory procedures

We prepare and support you throughout the regulatory milestones:

- Early interactions (ITF, INTERACT)
- Orphan Drug Designations (EU & US)
- Scientific Advice packages (e.g. EMA, NCA, MHRA, FDA)
- Pediatric Investigational Plans (EU, UK PIPs & US PSPs)
- ATMP Classifications & Certifications
- GMOs Assessments
- PRIME designation

Other tailored regulatory services.
Contact us to discuss your specific regulatory needs.

ASPHALION
Knowledge from experience

Preparation of Clinical Trial Applications

Supporting your journey from first-in-human studies and beyond

- Clinical trial protocol design and review
- IMPDs & IBs preparation and updates
- INDs preparation and updates
- Guidance and support along the procedure

ASPHALION
Knowledge from experience

Marketing Authorisation Expertise

Navigating global submissions with confidence

Preparation of dossiers for:

- All regions, type of procedures and legal bases

Including:

- Modules 1–5 preparation
- Pre-submission meetings
- Agency responses
- Dossier updates and adaptations
- Variations management

Clear. Compliant.
Compelling. **Always**.

Your Trusted Partner

Why Asphalion?

- **Strategic vision**
- **Regulatory expertise**
- **Scientific precision**
- **Partnership mindset**

Let’s build your regulatory strategy together.

ASPHALION
Knowledge from experience

Drug development is complex.
Your regulatory strategy shouldn’t be.

Contact us:

info@asphalion.com