

# 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.**



# 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




# 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.



# 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



# 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

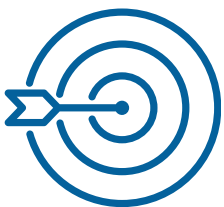
## Why Asphalion?



**Strategic  
vision**



**Regulatory  
expertise**



**Scientific  
precision**



**Partnership  
mindset**

**Let's build your regulatory strategy together.**



Drug development is  
complex.  
**Your regulatory  
strategy shouldn't be.**

**Contact us:**

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