ASPHALION
Knowledge from experience

Your partner for technology implementation and end-to-end product life-cycle support

NCE | Biologics | ATMPs | Medical Devices | IVDs

Lead Candidate → **Non-Clinical** → **Clinical** → **Dossier preparation** → **Market Authorization**

Regulatory Roadmap

- Regulatory strategy
- Feasibility assessments
- Gap analysis

- Support in Scientific Advice meeting (EMA, FDA, NCA)
- SME & Orphan Drug designation process
- Clinical Trial Application & CTIS
- IMPD + IB
- IND, PIPs/iPSPs, GMOs
- Scientific, Medical and Regulatory writing
- Complete vigilance study

- Pre-submission meeting
- Medical writing for preclinical and clinical section (M2-5)
- CMC writing (M3)
- eCTD publishing
- Transparency

- Centralised procedure management
- Translations management
- Pharmacovigilance
- Life cycle management
- Data management

ASPHALION'S TRACK RECORD

25+ YEARS
2,500+ CLIENTS
50+ COUNTRIES
10,000+ PROJECTS
190+ TEAM MEMBERS

Related Data Management Services

xEVMPD
- Authorised Medicinal Product
- Investigational Medicinal Product
- 3rd acknowledgement
- Pack size split

SPOR
- SMS
- OMS

Eudravigilance
- Registrations

ISO IDMP compliance:
- Consulting and Strategy
- Data Management
- IDMP readiness
- Regulatory intelligence

PMS:
- Review and remediation of migrated PMS data
- MVP dataset preparation aligned with EMA Roadmap
- Data enrichment & maintenance

Trainings

Advisory support during implementation of:
- RIMs
- DMS
- eCTD tools

Overall Data Management:
- Preparation
- Migration
- Validation

Regulatory Data Management during product lifecycle

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