Asphalion End to End support during product lifecycle

ASPHALION
Knowledge from experience

Drug discovery → **Non-Clinical** → **Clinical** → **Dossier preparation** → **Market Authorization** → **Post-Authorization**

- Regulatory Roadmap
- Regulatory strategy
- Feasibility assessments
- Gap analysis

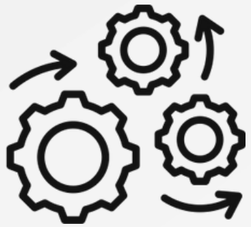
- Support in Scientific Advice meeting (EMA, FDA, NCA)
- SME & Orphan Drug designation process
- Clinical Trial Application & CTIS
- IMPD + IB
- IND, PIPs/iPSPs, GMOs
- Scientific, Medical and Regulatory writing

- Pre-submission meeting
- Medical writing for preclinical and clinical section (M2-5)
- CMC writing (M3 & M2.3)
- eCTD publishing
- Data disclosure

- EU (CP, DCP, MRP, RUP and NP) ; MHRA (IRP, NP); US (ANDA, BLA, NDA); ACCESS Consortium; and RoW procedure management
- Translations management
- Life-Cycle Management
- Variations management

CMC Gap Analysis | Feasibility Assessments | Strategic Consulting | CMC writing during development | CMC writing for registration and life-cycle

Experience



Continuous Improvement

Vision

Pharmacovigilance Drug Safety for Clinical Trials | EU-QPPV, PSMF, RMP and PV agreements | Case management, safety reports

Regulatory Operations

xEVMPD:
- New MAs
- Variations
- Investigational products (IMP)

SPOR:
- SMS
- OMS Registrations
- QC Eudravigilance registrations

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

Implementation of:
- CTMS, RIMS, DMS, eCTDtools, etc.
- Overall Data Management: Preparation, Migration , Validation
- Active Regulatory Review

eSubmissions:
- eCTD Publishing & eSubmission
- Document & Compilation
- Software Implementation & Audits
- Regulatory Intelligence
- Trainings