ASPHALION
Knowledge from experience

Regulatory solutions in the UK

Asphalion offers Regulatory Solutions in the United Kingdom and support with MHRA Requirements. Choose Asphalion as your local partner in the UK!

STRATEGIC AND OPERATIONAL SUPPORT

- Acting as your regulatory contact with MHRA
- Establish your SME status
- Responsible Person for Import (RP-I)

PRE-APPROVAL SUPPORT

- National Scientific Advice with MHRA
- UK Orphan drug designation (ODD) application
- Pediatric Investigational Plans within the UK framework
- Clinical Trial application

REGISTRATION AND AUTHORIZATION

- Dossier gap analysis and update of CMC, non-clinical and clinical sections for UK submission
- National procedures in UK; accelerated and rolling reviews
- Elaboration of CTD and regional requirements
- Submission in UK through MHRA Portal

POST-COMMERCIALIZATION

Lifecycle outsourcing:

- Variations, renewals, and notifications
- Complete portfolio maintenance
- Management of labelling changes and mock-ups
- Promotional material review

Local support for pharmacovigilance:

- Acting as your UK-QPPV
- Acting as your National Contact Person in UK (NCP-UK)
- Support in the elaboration of your local PV SOPs
- Preparation of PSMF-UK
- Holding your PSMF-UK at Asphalion location
- Local Case Management and submission of adverse events to MHRA
- Submissions of PSURs to MHRA
- Local Regulatory Intelligence
- PV training