ASPHALION
Knowledge from experience

Veterinary Services

Asphalion is aware of the increasing regulatory requirements for **Veterinary Products.**
Thanks to our expertise in this field, we can help you with the following **regulatory activities:**

REGULATORY AFFAIRS - MEDICAL WRITING

- GAP Analysis of veterinary medicinal product dossiers (in line with compliance with EU requirements)
- Generic/hybrid/complete marketing authorisation applications
- Pharmacological/biological veterinary medicinal products (immunological and non-immunological)
- Contact with authorities
- Marketing authorisation (MA) modifications, renewals and transfers
- Submission of maximum residue limits (MRL dossiers)
- Limited Market application (Limited Market)
- Requests for scientific advice (national or EMA)
- Preparation of development plans (timelines and budgets)
- Quality development (design of validation processes, validation of analytical methods, design of stability studies, etc.)
- Design of pre-clinical studies
- ERA reports/URA reports
- Investigational Veterinary Drug Application
- CRO selection
- Clinical trial applications, study protocol design, monitoring and study report
- Dossier writing and compilation

eCTD PUBLISHING - eSUBMISSION

- Publishing and submission of veterinary dossiers, in VNeeS format, for all types of EU procedures, including national and centralized procedures.
- eCTDpublishing and submission (in particular cases: ASMF of antibiotics for human/veterinary use)
- Submissions via CESP/EMA gateway portals
- Publishing and submission of veterinary master files (VMF) to the US FDA

DATA MANAGEMENT - RIMS

- Maintenance of UPD database
- Development of SOPs for compliance with UPD database
- RIMS Implementation
- Wide-ranging support for the implementation of RIM systems: design of migration plan, data mapping, data cleaning, gap analysis, execution for migration, validation and trainings

PHARMACOVIGILANCE

- Preparation of the PSMF
- Acting as QPPV
- Case management, including reporting through EvVet
- Signal management, searches and audits
- Specific training
- Development of veterinary SOPs

For further information, please contact: info@asphalion.com