

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 & LIFE-CYCLE MANAGEMENT

- Design of **pre-clinical** studies.
- Preparation of development plans (timelines and budgets).
- **CRO** selection.
- Investigational Veterinary Drug Application.
- **Clinical trial applications**, study protocol design, monitoring and study report.
- **Quality development** (design of validation processes, validation of analytical methods, design of stability studies, etc.).
- Dossier writing of **Pharmacological/biological** veterinary medicinal products (immunological and non-immunological).
- ERA reports/URA reports.
- Requests for scientific advice (national or EMA).
- **Limited Market** application (Limited Market).
- Submission of **maximum residue limits** (MRL application).
- **Marketing Authorization Applications** (Generic/hybrid/complete).
- **GAP Analysis** of veterinary dossiers (in line with compliance with EU requirements).
- Contact with authorities.
- Rollouts and **market expansion**.
- **Life-Cycle Management**: Variations on Marketing authorisations (MAs) - VRA & VNRA (UPD)
- Manage of **IRIS portal** for Centralised Procedures
- **Artwork** proofreading.
- Translation of local documents (SPC, Labelling & Package Leaflets) and QRD variations.

VNees & eCTD Publishing

- Publishing and submission of veterinary dossiers, in **VNeeS** format, for all types of EU procedures, including **national and centralized procedures**.
- **eCTD publishing and submission** (including, in specific cases, ASMFs for veterinary antibiotics).
- 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**.