



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 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 **VNeS** format, for all types of EU procedures, including **national and centralized procedures**.
- **eCTD publishing 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**.