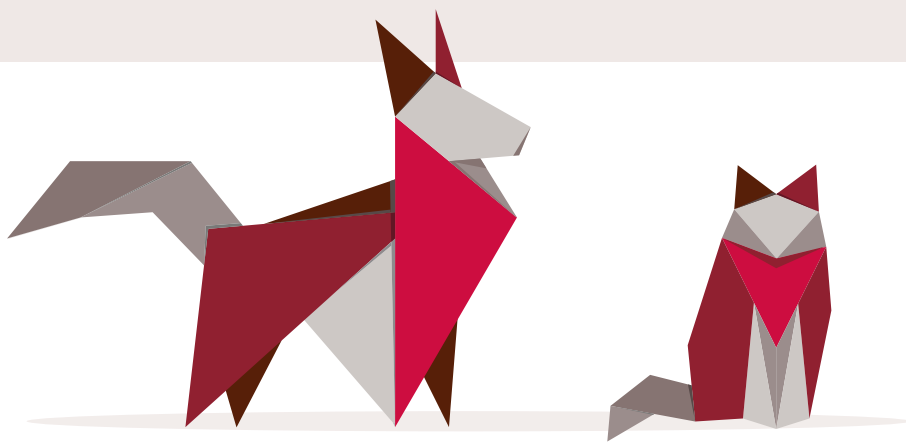


ANIMAL HEALTH SOLUTIONS

WHERE QUALITY MEETS EFFICIENCY



AT REGIVET, IT'S NOT JUST ABOUT TICKING BOXES

Regivet is your trusted partner in veterinary pharmaceutical development and registration across Europe. As an independent animal health consultancy and Contract Research Organization (CRO), we specialise in delivering expert guidance and comprehensive solutions tailored to your needs. Our hands-on, flexible approach ensures a smooth path from development to approval, and beyond.



PRODUCT DEVELOPMENT

END-TO-END DEVELOPMENT PROCESS FROM CONCEPT TO MARKET

Together, we find the right path

- Feasibility assessment of your product ideas
- Patent screening, freedom to operate
- Drug development plan

We perform pharmaceutical development activities in-house

- Formulation development and reverse engineering
- Expertise across multiple dosage forms
- Analytical method development and validation
- VICH stability studies

We can help you find the right partner

- Procurement of high quality APIs and materials
- Support of technology transfer to your CMO
- Reliable CMO/CRO selection
- Vendor management



PRECLINICAL & CLINICAL SERVICES

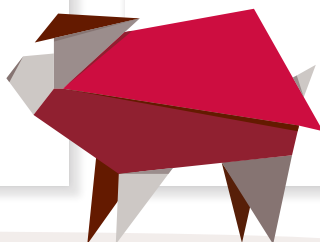
FULL SUPPORT FOR PRECLINICAL AND CLINICAL STUDIES IN VETERINARY DRUG DEVELOPMENT

We support your preclinical programme from early development to pivotal regulatory studies

- Formulation of non-GLP test products
- CRO selection
- Study design
- Protocol development and review
- Study management
- Report review

We conduct high-quality clinical research projects, on time and within budget

- Study design
- Protocol/DCF/eCRF development and review
- Database design
- Recruitment of study sites/study personnel
- Clinical Trial Application
- Preparation of IVP
- Study management
- Data management (EDC/Paper)
- Monitoring
- Statistics
- Scientific writing (report and publications)



Bioequivalence, PK studies
TAS, residue studies
Clinical field studies
Post registration/marketing studies
Palatability studies



REGULATORY AFFAIRS

**SUPPORT THROUGH EVERY STAGE OF THE
AUTHORISATION PROCESS OF VETERINARY
MEDICINAL PRODUCTS**

We define the best regulatory strategy

- In-depth knowledge of the EU regulatory landscape
- Tailored strategic advice on the optimal submission route, realistic timelines and effective authority interactions
- Pre-submission meetings and scientific advice

We prepare and submit your dossier

- Compilation and submission of compliant dossiers, including high-quality expert reports
- Management of EU procedures (CP, DCP, MRP, SRP, NP), with close follow-up until approval
- Administrative support and translations

We support your lifecycle management

- Efficient handling of variations and updates with full regulatory oversight



CONTRACT ANALYSIS & QUALITY CONTROL

**RELIABLE TESTING YOU CAN SUBMIT WITH
CONFIDENCE**

We perform pharmaceutical quality control testing

- Identity, assay and related substances testing
- Dissolution, hardness, disintegration and friability testing
- Karl Fischer titration, FTIR and UV/VIS analysis
- pH, melting point, viscosity and particle size testing
- Batch release analysis

We conduct stability studies

- Long-term and accelerated stability studies according to VICH GL3
- Ongoing stability studies
- Photostability studies according to VICH GL5
- Freeze-thaw cycling studies
- In-use stability studies

We deliver independent, GMP-compliant results

- EU GMP-certified laboratory
- Ph. Eur., USP and validated in-house methods
- Independent and unbiased testing
- Results delivered within agreed timelines

LESS COMPLEXITY MORE CLARITY REAL RESULTS

AT REGIVET, WE'RE NO-NONSENSE

- Hands-on, flexible and efficient
- Clear language - no jargon, no buzzwords
- Straightforward communication - honest and direct
- We keep it short, sharp and focused
- And yes - we're not afraid to say no when needed

MORE THAN 80 SUCCESSFUL EUROPEAN
PRODUCT AUTHORISATIONS ACHIEVED WITH
A GREAT TEAM OF EXPERTS



LET'S CO-CREATE YOUR NEXT VETERINARY PRODUCT!



REGIVET

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