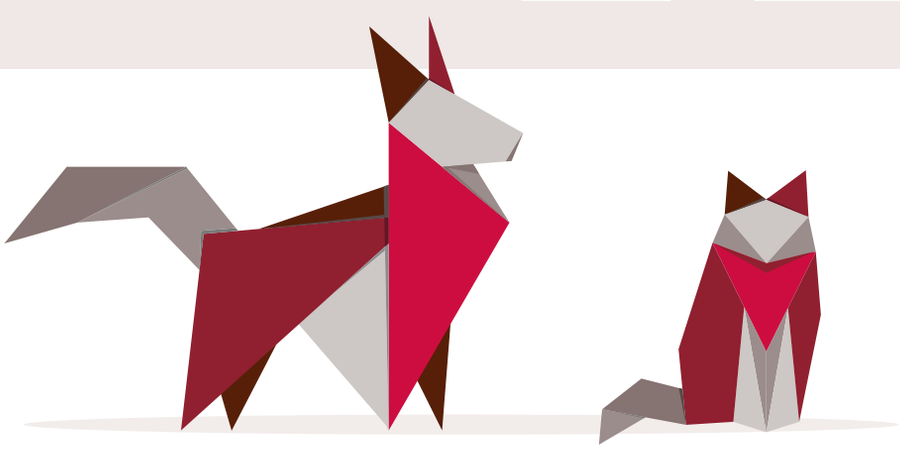
# ANIMAL HEALTH SOLUTIONS

**WHERE QUALITY MEETS EFFICIENCY**



Regivet

# 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 specialize 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**

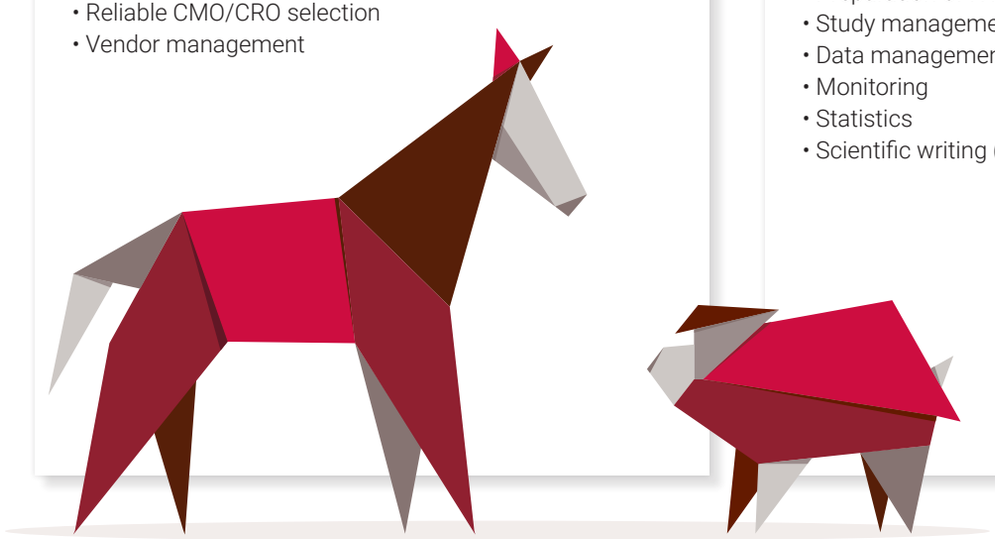
- Feasibility assessment of your product ideas
- Patent screening, freedom to operate
- Drug development plan

**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 PRE-CLINICAL AND CLINICAL STUDIES IN VETERINARY DRUG DEVELOPMENT

**We support your preclinical program 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

Regivet

## 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 life cycle management**

- Efficient handling of variations and updates with full regulatory oversight

## QUALITY CONTROL & MICROBIOLOGY SERVICES

### A HIGHLY QUALIFIED TEAM OF ANALYTICAL CHEMISTS AND MICROBIOLOGISTS

**We perform quality control tests**

- Physical and chemical testing of raw materials (human & veterinary use) and finished products
- Import testing and batch release analysis
- Ongoing stability studies under regulatory guidelines

**We offer a full range of microbiological services**

- Bioburden testing/total viable count/specified microorganisms
- Sterility testing
- Preservative efficacy testing
- Endotoxin testing
- Microbiological potency assays
- Water quality analysis

**We provide specialized support & consultancy**

- Advice on test methods and regulatory specifications
- Tailored problem-solving for microbiological and QC challenges

MIA numbers

2924-F (veterinary)

109627 F (human)

# 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 IN 2 LOCATIONS

**LET'S CO-CREATE YOUR NEXT VETERINARY PRODUCT!**

Regivet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