

Animal Health



ABOUT KYMOS

Kymos is a CRO that provides high quality analytical services in small molecule and biologic fields for different industries:

- Biotechnology
- Pharma
- Veterinary
- Phytopharma
- Nutraceuticals
- Cosmetics

Our main objective is to be part of your R&D and quality control department, building up long term partnerships.

Kymos and its affiliated company Pharmaprogress were founded in 2001 by professionals with more than 10 years' experience in key R&D departments.

Kymos has significant international operations in several countries, with a strong presence in Central and Southern Europe, and important activities in Asia.

Location

Kymos has two European sites. The headquarters and the main laboratories are located in the Parc Tecnològic del Vallès, Barcelona, which is one of the most important poles for scientific and technological companies in Spain, close to the Autonomous University of Barcelona and Synchroton Alba.

Alternative laboratories oriented to CMC services are located in Ancona, Italy, under the trademark Pharmaprogress.

Our commitments

We understand our clients concerns far beyond the service given to them as we have gone through similar professional situations and we speak the same language.

We are fully aware of our partners needs in terms of:

- Quality
- Reliability on timings
- Added value service
- Comprehensive offer
- Competitive prices

Quality assurance

Kymos complies with the current VICH guidelines and with FDA, EMA and PMDA regulations.

A Quality Assurance Unit and a Qualified Person is available at the company.

We have GLP and GMP certifications and authorization as importer and manufacturer in Quality Control for human, veterinary and investigation medicinal products.

Animal Health

Residue depletion and Bioequivalence studies.
Analytical Development and Quality Control.
Pharmaceutical and Biological drug products.
GMP and GLP certification.



PRECLINICAL STUDIES

Kymos is a bioanalytical CRO who provides comprehensive preclinical veterinary studies under GLP for regulatory purposes in alliance with other CROs experts in animal housing and study management: CLINOBS (livestock) and ISOQUIMEN (pets).

KYMOS services

- Development and validation of analytical methods to quantify drugs, metabolites, metals or biomarkers in different animal matrices (plasma, milk and tissues)
- Compliance of VICH, EMA and FDA guidelines
- Two bioanalytical platforms available: mass spec and immunology
- Toxicokinetics, Pharmacokinetics and Bioavailability studies
- Immunogenicity studies
- Residue Depletion and Bioequivalence studies
- Data analysis and PK reporting (Phoenix WinNonlin®)
- Wide experience with most used drugs: cephalosporins, macrolides, tetracyclines, olymyxins, fluoroquinolones, sulfamides, coccidiostats, antihelmintics, NSAIDs, steroid, hormones...



CLINOBS and ISOQUIMEN services

- Study Design under GLP compliance
- Regulatory support in front of Health Authorities
- Animal welfare and Ethical Committee Management
- Extraction of samples: blood (and derivatives) and any kind of tissue
- · Animal housing, feeding, weighing, quarantine, slaughter
- Studies: pre-clinical, clinical, immunological, and nutritional



CLINOBS experience

Cattle, swine, horses, sheep, poultry, turkeys and rabbits



ISOQUIMEN experience

SPF cats, conventional and SPF dogs, New Zealand White rabbits and ferrets

CMC SERVICES

Kymos is a reliable partner to outsource analytical development and quality control services under GMP for APIs, drug products, premixes and feed. Kymos has a large experience and state of the art instrumentation for small molecules, biologics and vaccines.









Method development, validation and transfer

- Identification
- Assay and related substances
- Content uniformity
- Elemental impurities, genotoxic impurities, residual solvents
- Formulation testing
- Potency assay of vaccines

Stability studies

- Photostability
- ICH stability studies (zones from I to IVb)
- In use, holding time and transportation stability
- On-going stability program

Microbiology testing

- Sterility Testing (isolation technology)
- Microbial limit test: TAMC and TYMC
- Microorganism Identification
- Minimum Inhibitory Concentration (MIC)
- Method suitability and validation
- Challenge test
- Bacterial endotoxins
- Particulate matter: visible and subvisible particles
- Water microbiological control
- Biocicles effectiveness

Quality Control and Batch Release Certificates

- Excipients
- APIs
- Intermediates
- Finished drug products
- Premixes and feed





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