KYMOS

Bioanalysis

- Clinical trials conducted in European centers
- FDA and EMA inspected, and GCP and GLP compliance
- One-stop shop service including batch release

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BIOANALYSIS

KYMOS counts with state-of-the-art bioanalytical laboratories **GLP certified** and **GCP compliant**. These new premises within the Vallès Technological Park (Barcelona) are periodically inspected by sponsors and regulatory authorities of **EMA** and **FDA**.

KYMOS has a long track record in bioanalysis specially for innovative drugs with wide experience in the development of challenging methods for drugs, their metabolites and biomarkers, conducting method validation following the fit-for-purpose concept, ensuring the suitability of validation level for the intended scope of the study, and carrying out the analysis of preclinical and clinical samples adjusting the timelines and resources to the client requirements. We also offer calculation and statistics of the pharmacokinetic parameters using the validated **Phoenix® WinNonlin®** software.

BIOANALYSIS OF SMALL MOLECULES

KYMOS **mass spectrometry platform** is specialized in method development, validation and sample analysis of **highly challenging projects:** low stability compounds, therapeutic peptides and small proteins, extremely low limits of quantification, endogenous compounds, metal and organometallic drugs, multiple metabolite profiling, complex methods involving derivatization procedures to increase sensitivity.

Our experience on bioanalysis covers the following fields:

- Generic and fast bioanalytical methods for *in vivo* and *in vitro* ADMET screening.
- Specific bioanalytical methods for preclinical **toxicokinetic**, **bioavailability** and **pharmacokinetic** studies.
- **First in man** and **dose escalation** studies.
- Bioanalytical methods for human clinical pharmacokinetics including clinical pharmacology, bioavailability and **bioequivalence studies** (from clinical phase I to IV).
- Studies of drug-drug interaction.
- Bioanalytical support to PK/PD studies.
- Biomarker studies.
- **Residue depletion studies** in different tissues and species for veterinary medicines.
- Bioequivalence studies for veterinary medicines.
- Dietary supplement and phytopharmaceuticals absorption studies.
- Bioanalytical methods for *in vitro* **percutaneous absorption** studies.

KYMOS has a large pool of equipment in terms of **number of instruments** and **variety of instrumental techniques** available to face projects with a high number of samples involved:

- UHPLC- and HPLC-MS/MS: Sciex API 6500+, API5500, API4000, API3200 and Agilent 6490
- UPLC-HRMS: QTof Xevo G2S
- ICP-MS Agilent 7700 and 7800

BIOANALYSIS OF PROTEINS

KYMOS offers in method development by **mass spectrometry** with triple quadrupole and QToF mass spectrometers to measure the intact proteins and peptides or tryptic digested proteins of all sizes quantifying selected diagnostic peptides. However, **immunological techniques** continue to be the gold standard for the quantitation of large proteins in biological fluids.

KYMOS has experience in development, validation and sample analysis by immunoassay of **peptides, recombinant proteins, mAbs, ADCs**, and **biosimilars**. Different platforms are available to be used depending of the molecule:

- **Radioimmunoassay (RIA)** using I^{125} radiotracers
- **ELISA:** direct, sandwich, bridge or competitive using different detection techniques such as colorimetric, fluorescence or time resolved fluorescence
- **Electrochemiluminiscence (ECLA)** by Meso Scale Discovery (MSD®) platform

KYMOS offers a full development service including the production of the **polyclonal antibodies** and labelled reagents necessary for the assay.

IMMUNOGENICITY

Biologic drugs may have a high potential to induce immune response which can impact on pharmacokinetics, efficacy, cross-reactivity and side effects. Due to these potential impacts on efficacy and safety, immunogenicity has become a key issue for health authorities. KYMOS provides services covering the different development phases:

- **Binding assays for Anti-Drug Antibodies (ADA):**
  - Screening assays for the detection of positive samples
  - Confirmatory assays for ruling out false positive results
  - Isotyping assays to determine the ADA isotypes
  - Titration assays to quantify the immune response
- **Neutralizing assays** to assess the drug function inhibition capabilities of the ADA using specific cell assays
- **Cellular immune response** using suitable **cell-based assays**

The same techniques used for protein bioanalysis are used for ADA testing (RIA, ELISA and ECLA). In addition, KYMOS provides **label-free methods for interaction and binding studies** using **Surface Plasma Resonance** technology (Biacore®).