



## Alliance Pharma "DMPK" Services

*Your trusted partner in  
pharmaceutical development*

### OUR COMPANY

Alliance Pharma is a contract research organization (CRO) specializing in full Drug Metabolism and Pharmacokinetic (DMPK) NDA filings support and bioanalytical services for both small molecules and biomolecules.

We achieve our success through an emphasis on ethical study conduct and compliance to regulatory guidelines and through our strong technical expertise. Our management and scientific team is comprised of members from well known and respected CROs, biotechnology and major pharmaceutical companies.

### OUR PHILOSOPHY

We are committed to meet even the most challenging technical requirements and the most demanding schedules. Our mission is to build a trusted partnership with our clients by offering them high quality service, competitive pricing and quick turnaround time. We believe our success is measured by the success of our clients.

### OUR EXPERTISE

Our extensive and diverse industrial experience includes:

- GLP and GCP compliance
- New drugs, metabolites or generic drug assays
- Small molecule LC-MS/MS analysis
- Large molecule immunoassays
- Small molecule metabolite profiling and identification
- Pharmacokinetic modeling and design

### FOR MORE INFORMATION

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[alliancepharmaco.com](http://alliancepharmaco.com)

# Services

## BIOANALYSIS (LC-MS/MS)

- Method feasibility
- Method development
- Method Validation
- Method transfer
- Dried blood spots
- Sample analysis

## BIOPHARMACEUTICAL ANALYSIS

- Method development, validation and sample analysis
- Ligand binding assays
  - ELISA—indirect, bridging, sandwich and competitive
  - Immunoassay with Absorbance, Luminescence, Chemiluminescence, Electrochemiluminescence (ECL), Fluorescence
  - Radioimmunoassay (RIA)
- Immunogenicity assays
  - Screening
  - Confirmation (immunodepletion)
  - Titer assessment (quantification)
  - Cell-based neutralizing antibody (Nab) determination
- PK assays for large molecule in different matrices
- Cell based bioassays
  - Cell proliferation/inhibition, apoptosis
  - Reporter gene assays
  - Fluorescent polarization (FP), Time-Resolved Fluorescence (TRF)
  - Immunochemistry
  - Cytokine induction and inhibition
- Biomarkers
  - Single and multiplex biomarker panels
  - Genotyping
  - Mutation, methylation and SNP analysis

## SAMPLE ANALYSIS

- Nonclinical toxicokinetic (TK) studies
- Pharmacokinetic (PK) screening
- Clinical PK/bioavailability studies
- Bioequivalency studies
- Biomarker studies
- Drug-drug interaction studies

## PHARMACOKINETICS/TOXICOKINETICS

- Animal dosing
- Pharmacokinetic modeling and design
- Report writing

## DRUG METABOLISM (IN VITRO/IN VIVO)

- Metabolic stability, CYP induction, inhibition and reaction phenotyping
  - CYP450 induction in fresh human hepatocytes (in vitro) and rodent, dog and primate liver (ex vivo)
  - In vitro CYP450 inhibition (IC50 and Ki)
  - Identification of specific CYP450 enzymes involved in the metabolism of the test article
  - Species comparisons of in vitro metabolism in microsomes and hepatocytes
- Metabolite identification and profiling, including: accurate mass measurement
- Plasma protein binding & blood cell partitioning

## FACILITIES AND EQUIPMENT HIGHLIGHTS

- 38,600 sq. ft. of dedicated space
- Located in northeastern Pennsylvania (outside Philadelphia)
- Meso Scale Discovery SECTOR Imager 6000
- Microplate readers with fluorescence, luminescence and absorbance detection
- Microbeta scintillation and luminescence counter
- Level III bio-safety hoods
- Cell culture incubators
- 6 PE Sciex LC-MS/MS systems
- 6 Shimadzu HPLC system
- 2 UPLC systems
- 4 Thermo Water injected CO<sub>2</sub> Incubators
- 2 Homogenizers
- Radiochemical detectors