



*Reliable, high quality laboratory data is pivotal to the success of your drug development process. At Eurofins, laboratory science is our sole focus. Our mission is to contribute to global human health and safety by providing our customers with high quality laboratory and advisory services to attain the most cost effective and efficient solutions for your bioanalytical needs.*

*Eurofins is committed to providing the highest quality services, accurate, timely results, and expert advice from our highly qualified team of experienced scientists in the fields of pharmacokinetics, immunogenicity testing and biomarker-mediated drug development.*

## Worldwide excellence in bioanalysis

### Pharmacokinetics

- Method development and transfer
- Method validation
  - Small and large molecules
  - Biopharmaceuticals, including:
    - Monoclonal Antibody (MoAb) drugs
    - Oligonucleotide drugs
    - Biologics
    - Biosimilars
- Toxicokinetics
- Human pharmacokinetics
  - First in man: on-line analysis
  - Bioequivalence
  - Daily Therapeutic Drug Monitoring on three continents
  - Statistical analysis, PK modeling and simulation

### Immunogenicity testing

- Vaccine-mediated immunogenicity (non-infectious disease)
- Immunogenicity testing of biopharmaceuticals and biosimilars
- Screening and confirmation assays
- EliSpot assays
- Functional bioassays (cell based assays)

### Biomarker-mediated drug development

- PD – target engagement biomarkers, proof-of-mechanism and proof-of-concept studies
- Feasibility assessment and scientific consultation
- Fit-for-purpose validation and analysis of commercially available biomarker assays
- Biomarkers for kidney injury
- Biomarkers in exotic matrices (e.g. sputum, stool)



## Applied technologies

- LC-MS/MS
- ELISA
- MSD
- Luminex
- Flow cytometry
- **Dried Blood Spots**
  - Method development and validation
  - Analysis of small and large molecules using DBS sampling technique
  - [www.driedbloodspots.com](http://www.driedbloodspots.com) for detailed information and methods

## Bioanalysis integrated with Global Central Laboratory

- Synergetic approach of bioanalysis integrated in Global Central Laboratory
- Clinical trial supporting services, including:
  - Sample management and long term storage
  - Logistic support and courier management
  - Project and data management
  - Investigator site support

All three Eurofins Bioanalysis laboratories are compliant to the OECD principles of Good Laboratory Practice (GLP). We offer *de novo* assay development, assay transfer and assay validation according to Bioanalytical Laboratory Practice – FDA guidance for Industry on Bioanalytical Method validation, Crystal City updates, EMA guideline on validation of Bioanalytical Methods, and published recommendations. Our laboratory sites are regularly inspected by both regulatory local agencies and Sponsors. Eurofins Bioanalysis laboratories deploy Watson® Bioanalytical LIMS.

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