eurofins | Bioanalytical Services

Biologics Done Right

How Similar is your Biosimilar?

Fast-track pre-qualified assays for characterization and analysis of Biosimilars

Background

Eurofins Bioanalytical Services is a biologics-focused, global leader in bioanalytical solutions providing over 20 years of industry-leading scientific expertise in comprehensive PK/TK, ADA, NAb, Biomarker assays and sample analysis for the world's largest pharmaceutical and biopharmaceutical companies.

Sample Analysis at the

RIGHT TIME & RIGHT PLACE

to satisfy data delivery requirements

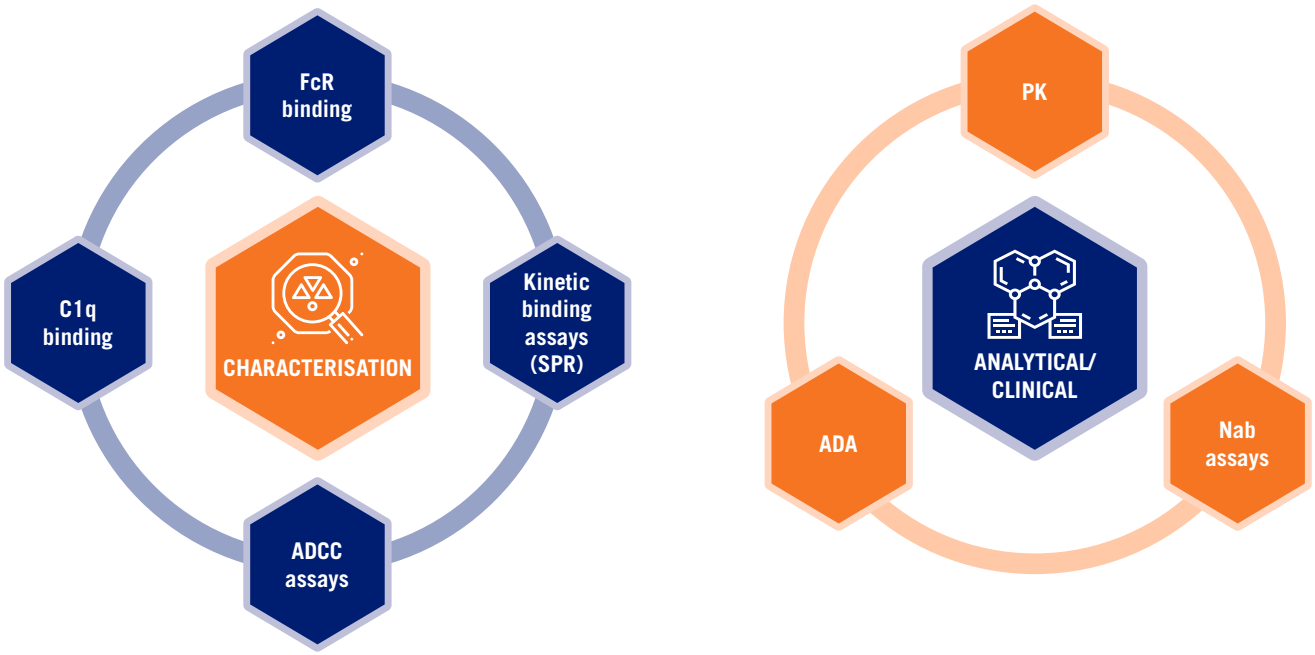
Streamline your R&D, regulatory, and bioanalytical needs with one provider

Eurofins Bioanalytical Services is an industry-leading expert in biosimilar testing services for the biopharmaceutical industry. Alongside development, validation and analysis for other large molecules, we have developed significant expertise in the biosimilar niche, dedicating ourselves to the biological evaluation of therapeutic monoclonal antibodies, and offering a comprehensive range of off-the-shelf biosimilar testing services to support biosimilar development.

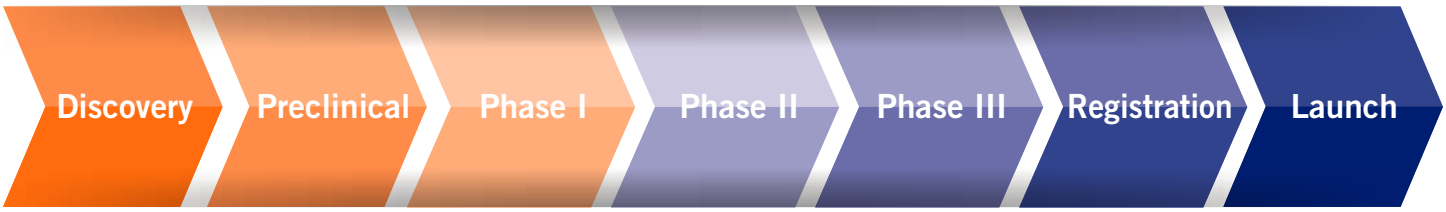
With years of experience in the performance of binding and cell-based assays utilising multiple platforms, coupled with ready-to-use methods, we provide superior expertise to reduce both time and cost of your biosimilar development programs.

With our regulatory knowledge and experience in product characterization, pharmacokinetics, and immunogenicity, for both innovator and biosimilars, we carry your project from Discovery through Phase III and beyond.

Industry-leading Development & Analysis



The Eurofins Advantage



PRE-QUALIFIED ASSAYS

Eurofins Bioanalytical Services offers GLP, GCP and GMP-compliant testing services, with a full range of pre-qualified assays (using innovator references) for exploratory and comparability testing of biosimilars.

FLEXIBILITY

We understand the unique requirements you have. From small or large sample numbers, short or extended timeframes, single or multiple assays, we will work with you to provide an analytical plan to meet the needs of your study.

Need some modifications to the assays, e.g., additional biosimilar-specific reagents for further validation? "One assay" or "two assay" approach? No problem. Bioanalytical and characterization packages are tailored to meet the distinct needs of biosimilar developers ensuring accuracy, adherence to standards and on-time delivery of critical data, no matter the size of the project.

REDUCED TIME AND COSTS

Using both pre-qualified assays and leveraging significant experience in biosimilar analysis means significantly reduced time in development/validation and lower costs for your project.

SCIENTIFIC AND REGULATORY EXPERTISE

Our Scientific Directors will discuss your project and needs before, during, and after the studies, providing scientific support as well as regulatory insights.

STATE-OF-THE-ART FACILITIES AND EQUIPMENT

With a facility spanning 52,000 sq feet, and over 60 staff fully dedicated to large molecule bioanalysis together with the most widely used platforms (ELISA, Luminex, MSD, Gyrolab, Biacore, Singulex) and automation, we are sure to be able to find solutions to meet your project requirements.

BEST PRACTICES AND REGULATORY GUIDELINES

Reliable data from a trustworthy partner are paramount to ensure the success of your projects and regulatory submissions. Eurofins follows the EMA and FDA guidelines in validation and analysis.

Streamline your R&D, regulatory, and bioanalytical needs with one provider

Generic name	PK	ADA	Nab	Fc Receptor binding	ADCC	C1q binding	Target binding
Adalimunab	•	•	•				
Bevacizumab	•	•	•	•		•	
Cetuximab	•	•		•		•	•
Epoetin alpha	•	•					•
Etanercept	•	•		•		•	•
Exanatide		•	•				
Filgrastim			•				
Somatotropin		•	•				•
Infliximab	•	•		•		•	
Insulin Lispro		•					•
Insulin Glargine			•				
Palivizumab	•	•		•		•	•
Rituximab	•	•				•	
TPO	•						
Trastuzumab	•	•		•	•	•	•

• Owned Method • Clinical Experience • In Development

Is your biosimilar drug not on the list? We are constantly assessing the needs of the market and expanding our service offer. Get in touch to discuss your project and we will provide you with an off-the-shelf assay or work with you for a customized solution.

Immunogenicity

- Assay development, method transfer, validation. Cut-point calculation
- Screen, Confirm, Titer. Advanced methodologies to address drug tolerance and soluble target interference
- Advanced cell based laboratory dedicated to GLP NAb assay development and sample analysis
- Experience and capacity for large volume sample analysis

Biosimilars

- Pre-developed assays for Trastuzumab, Bevacizumab, Cetuximab, Adalimumab, and more
- PK, Immunogenicity evaluation
- FcRN, FcγRI, II, III and C1q binding
- Cell based assays
- Receptor binding, proliferation, ADCC

Biomarkers

- GLP/GCP/CLIA assay development, method transfer, validation
- Exploratory sample analysis using kits from any vendor across a wide variety of platforms
- Luminex, ELISA, RIA, MSD, GyroLab, Flow Cytometry, Singulex
- Full flow cytometry capabilities to support GxP studies
- Immunophenotyping, pharmacodynamics
- Cytokine release assays

Pharmacokinetics

- Large molecule specialists, capacity for large volume sample analysis
- Clinical and Pre-clinical PK studies
- Exploratory / GxP
- Latest platforms including GyroLab and Singulex

Contact us today to discover how we can make the difference in your projects.

BioanalyticalServices@eurofins.com

US +1 636 362 7000

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About Eurofins Bioanalytical Services

Over 20 years of industry-leading global **Scientific Expertise** supporting the widest breadth of Biologics' clinical trials with PK/TK, ADA, NAb and Biomarker assays and sample analyses.

Versatile Performance and Project Management Excellence to adapt to a client's specific needs. Clinical or preclinical, regulated or non-regulated, assay development, qualification or validation; we custom design our support to match the client's program.

State-of-the art laboratory facilities in St. Charles, MO, USA providing **Global Reach and Capacity** to address clients' needs while simultaneously offering regionally-based solutions.

BioanalyticalServices@eurofins.com
eurofins.com/bioanalyticalservices