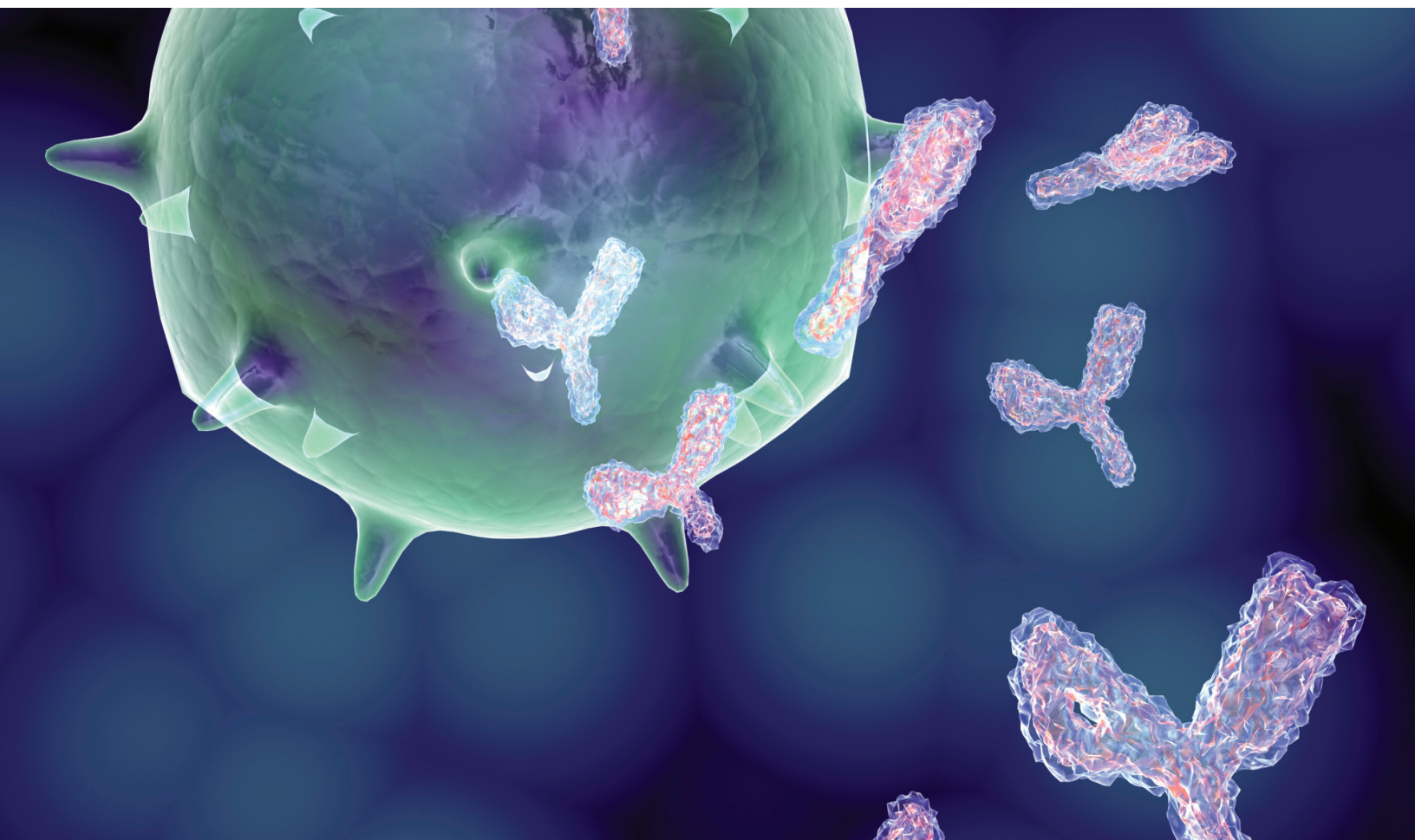


## How Similar is your Biosimilar?

**Fast-track pre-qualified assays for  
characterisation and analysis of Biosimilars**



**Specialists in Large Molecule Bioanalysis**

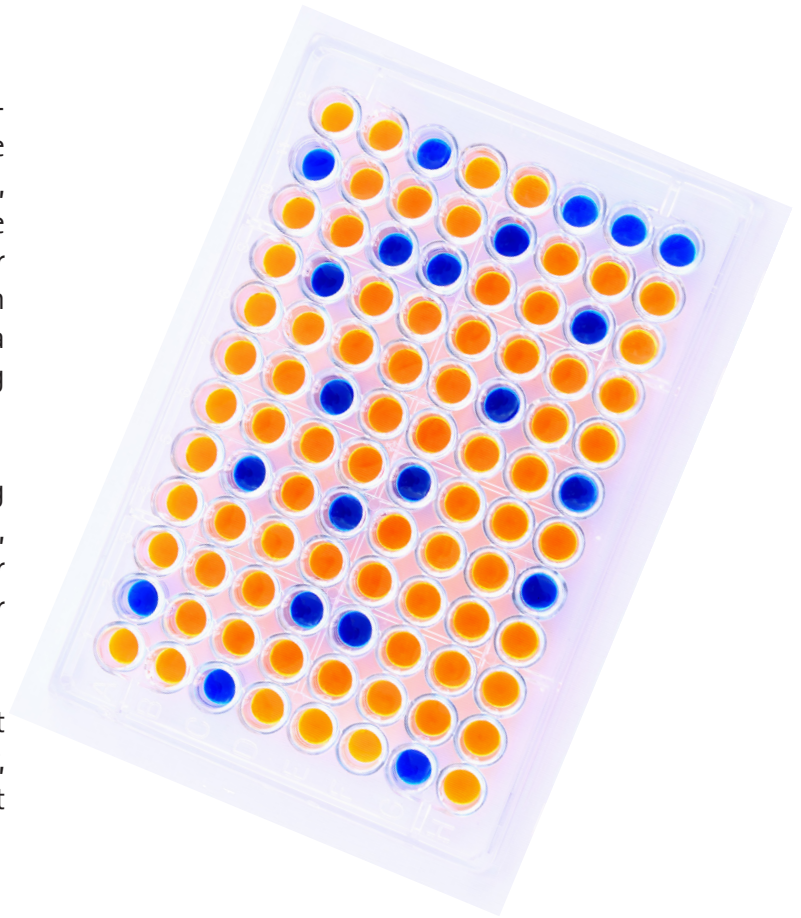
[eurofins.com/bioanalyticalservices](http://eurofins.com/bioanalyticalservices)

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

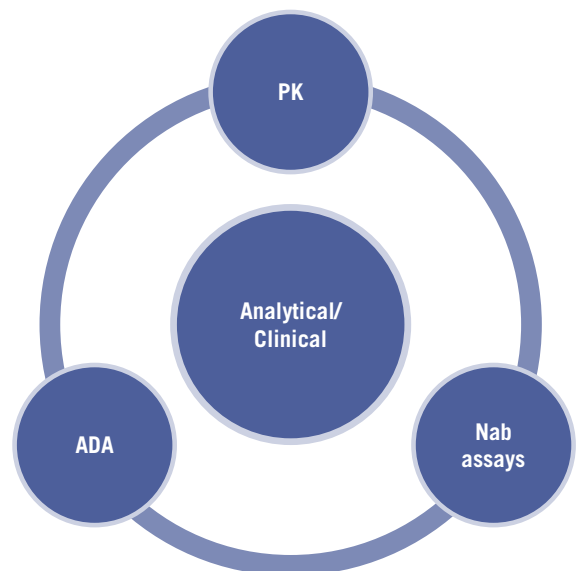
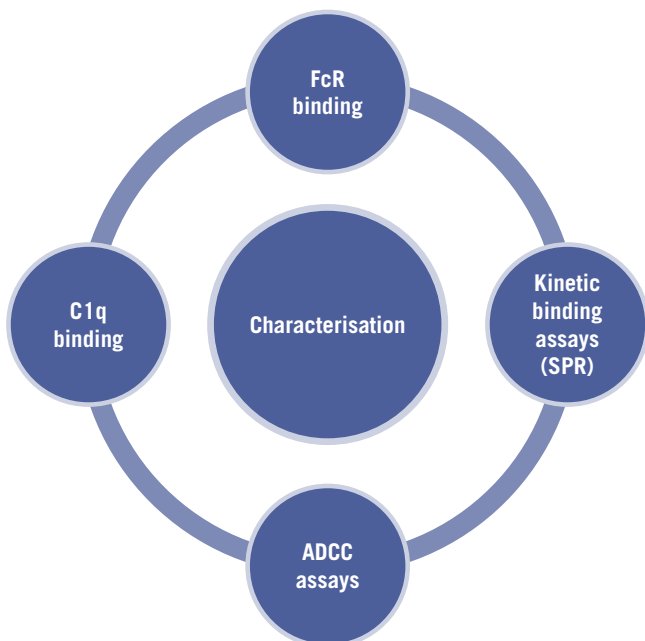
Eurofins Bioanalytical Services is an industry-leading expert in biosimilar testing services for the biopharmaceutical industry. Alongside development, validation and analysis for other large molecules, we have developed significant expertise in the biosimilar niche, dedicating ourselves to the biological 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

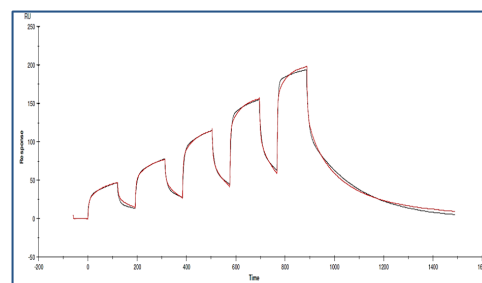
With two facilities spanning 60,000 sq feet, and over 130 staff fully dedicated to large molecule bioanalysis, together with the most widely used platforms (ELISA, Luminex, MSD, Gyrolab, Biacore, Singulex) and automation, we are sure to be able to find solutions to meet your project requirements.

## ▶ 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.



Biacore™ T200



# Expertise in simple and complex biosimilars

Generic name	PK	ADA	Nab	Fc Receptor binding	ADCC	C1q binding	Target binding
Adalimumab	●	●	●				
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.

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

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