Bioanalytical Solutions for Biologics, Biosimilars & Advanced Therapies

eurofins | Viracor BioPharma

Confident decisions. Faster development. Regulatory-ready data.

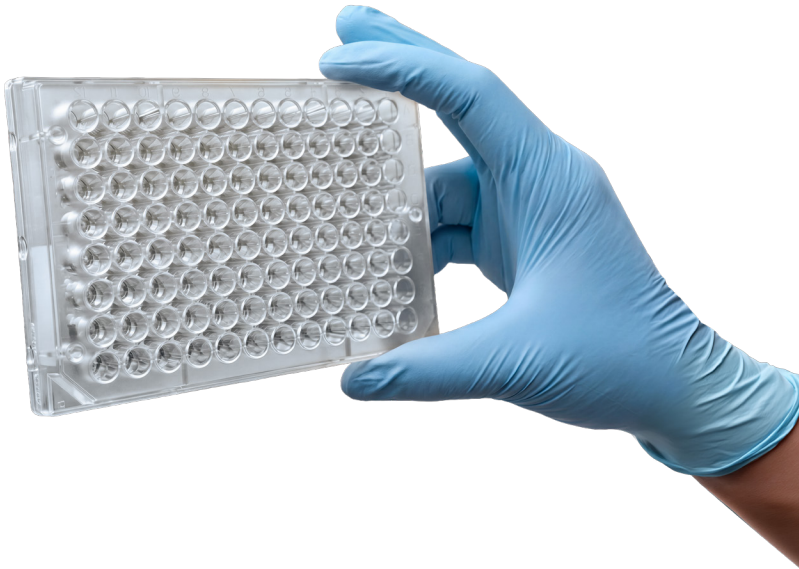
Eurofins Viracor BioPharma Services delivers **high-quality, biologics-focused bioanalytical solutions** that help sponsors move confidently from early development through late-stage clinical trials and post-approval.

As part of the **Eurofins Viracor BioPharma** organization, our bioanalytical team combines **deep scientific expertise, scalable global capacity, and proven regulatory strength** to generate the data that drives critical development and approval decisions.

Driving critical development and approval decisions with deep scientific expertise and proven regulatory strength from early development through post-approval.

At Eurofins Viracor BioPharma, we don't just test samples—we help de-risk

- **Biologics-first expertise** – Designed specifically for large molecules, complex modalities and emerging therapeutic formats with capabilities in plate reader assays, MSD, PCR and coming soon (2027) LCMS.
- **Regulatory confidence** – CLIA, GLP/GCP-compliant operations
- **Speed at scale** – Automation, optimized workflows, and global infrastructure to handle large sample volumes without compromise
- **True partnership** – Hands-on scientific collaboration to solve assay challenges before they become delays



*From **non-GLP feasibility studies to global Phase III programs and biosimilars**, we adapt to your science, timeline, and regulatory path.*

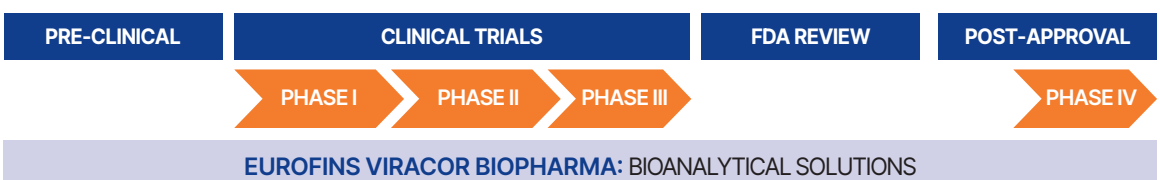
Integrated Bioanalytical Capabilities Across Drug Development

Preclinical | Clinical | Post-Approval

We support the full biopharmaceutical lifecycle with customized, fit-for-purpose bioanalytical solutions that evolve with your program.

Core Capabilities

- Pharmacokinetics (PK) / Toxicokinetics (TK)
- Immunogenicity (ADA & NAb)
- Biomarkers & Exploratory Endpoints
- Flow Cytometry & Functional Assays
- Biosimilar Bioanalytical & Characterization
- Precision Oncology and Sequencing
- Critical Reagent Development
- Polymerase Chain Reaction (PCR)
- Gene Expression



Pharmacokinetics & Toxicokinetics (PK/TK)

Data you can trust—when it matters most

PK/TK data is foundational to safety, efficacy, and dose-setting decisions. Our team brings decades of experience across nearly every biologic modality, providing reliable, decision-ready results.

Our PK/TK strengths

- Customized assay development, transfer, and validation
- High sensitivity and specificity for complex biologics and peptides
- Platform expertise (MSD®, Gyrolab®)
- Integrated support for critical reagents and antibodies

Result: *Clear exposure data, reduced development risk, and faster study progression.*

Immunogenicity & Neutralizing Antibody Testing

Regulatory-ready immunogenicity, designed for confidence

Immunogenicity assessment is no longer optional—it's critical. We support ~**70 immunogenicity programs annually**, helping sponsors meet evolving regulatory expectations while avoiding costly rework.

Comprehensive immunogenicity support

- Tiered ADA strategies from screening to confirmation and titration
- Neutralizing antibody (NAb) assays—ligand-binding or cell-based
- Positive control strategy development
- Drug tolerance and matrix effect mitigation

*With access to **hundreds of cell lines through the Eurofins network**, our NAb experts reduce technical risk and accelerate timelines.*

Biomarker & Exploratory Endpoint Solutions

Turn data into insight

We offer **protein, genomic, and flow cytometry-based biomarkers** that support proof-of-mechanism, patient stratification, and translational strategy.

Why sponsors choose us

- Flexible assay design: single-plex to multiplex
- Broad platform expertise (Luminex®, MSD, QuantStudio 7™, and ELISpot)
- Consultation-driven approach to ensure biomarker relevance
- Fit-for-purpose validation aligned to study phase

From early discovery to late-stage trials, we help ensure your biomarkers ***answer the right questions.***

Flow Cytometry & Functional Assays

Deep immune profiling. Actionable results.

Our flow cytometry team delivers high-content immune characterization to support immuno-oncology, cell therapy, and immunomodulatory programs.

Capabilities include

- High-parameter immunophenotyping
- T, B, NK, CAR-T, and myeloid cell panels
- Activation, exhaustion, and checkpoint markers
- Functional assays, intracellular cytokines, and Phosflow
- Receptor occupancy and rare event analysis

Predictive Cytokine Release Assays

Pre-qualified *ex vivo* assays provide **early safety insight**, helping sponsors identify cytokine release risk before clinical exposure.

Biosimilar Bioanalytical Excellence

Proven experience. Reduced uncertainty.

Eurofins Viracor BioPharma has extensive experience supporting **innovator and biosimilar development**, delivering tailored bioanalytical and characterization strategies aligned with current global guidance.

Biosimilar support includes

- PK, ADA, NAb, and biomarker assays
- Pre-qualified assays (e.g., adalimumab, trastuzumab, bevacizumab)
- Binding, neutralization, receptor occupancy, ADCC, and CDC assays

Outcome: *Confident comparability assessments and smoother regulatory interactions.*

Critical Reagent Development & Lifecycle Management

Strong assays start with strong reagents

Our dedicated reagent team ensures **consistency, performance, and traceability** throughout the life of your study.

Services include

- Generation and qualification of critical reagents
- Lot-to-lot comparability and requalification
- Secure reagent storage and tracking
- Conjugation, labeling, purification, and coupling expertise

This proactive approach helps protect timelines and data integrity.

Quality, Compliance & Performance — By the Numbers

Built to meet global regulatory expectations

- Independent QA aligned with **21 CFR Parts 11 & 58**
- CLIA, GLP/GCP-compliant operations
- Electronic training, documentation, deviation, and CAPA systems

Operational scale

- 250 active studies annually
- 50,000 clinical samples processed per year
- 20/10 business day standard turnaround (ADA / PK)
- 20 successful global client audits annually

As part of **Eurofins**, we are backed by the **global Eurofins network**, offering unmatched scientific breadth, scalability, and continuity across clinical development. **Our state-of-the-art laboratory** in the U.S. provides both global reach and regionally responsive service.

Let's Move Your Program Forward

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Advance Your Drug Development Strategy with Confidence

Partner with Eurofins Viracor BioPharma to generate high-quality, decision-ready data that accelerates development.

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