

# Explore the World of End-to-End Integrated Laboratory Services



BioPharma Services



Come explore the largest, wholly owned network of BioPharma dedicated laboratories in the world.

Discovery/Pharmacology

Early Clinical Development

Bioanalysis

Central Laboratory

Molecular & Infectious Disease

Allergy/Immunology

Anatomic Pathology

Genomics

Contract Development & Manufacturing

GMP Product Testing

# Eurofins BioPharmaceutical Services

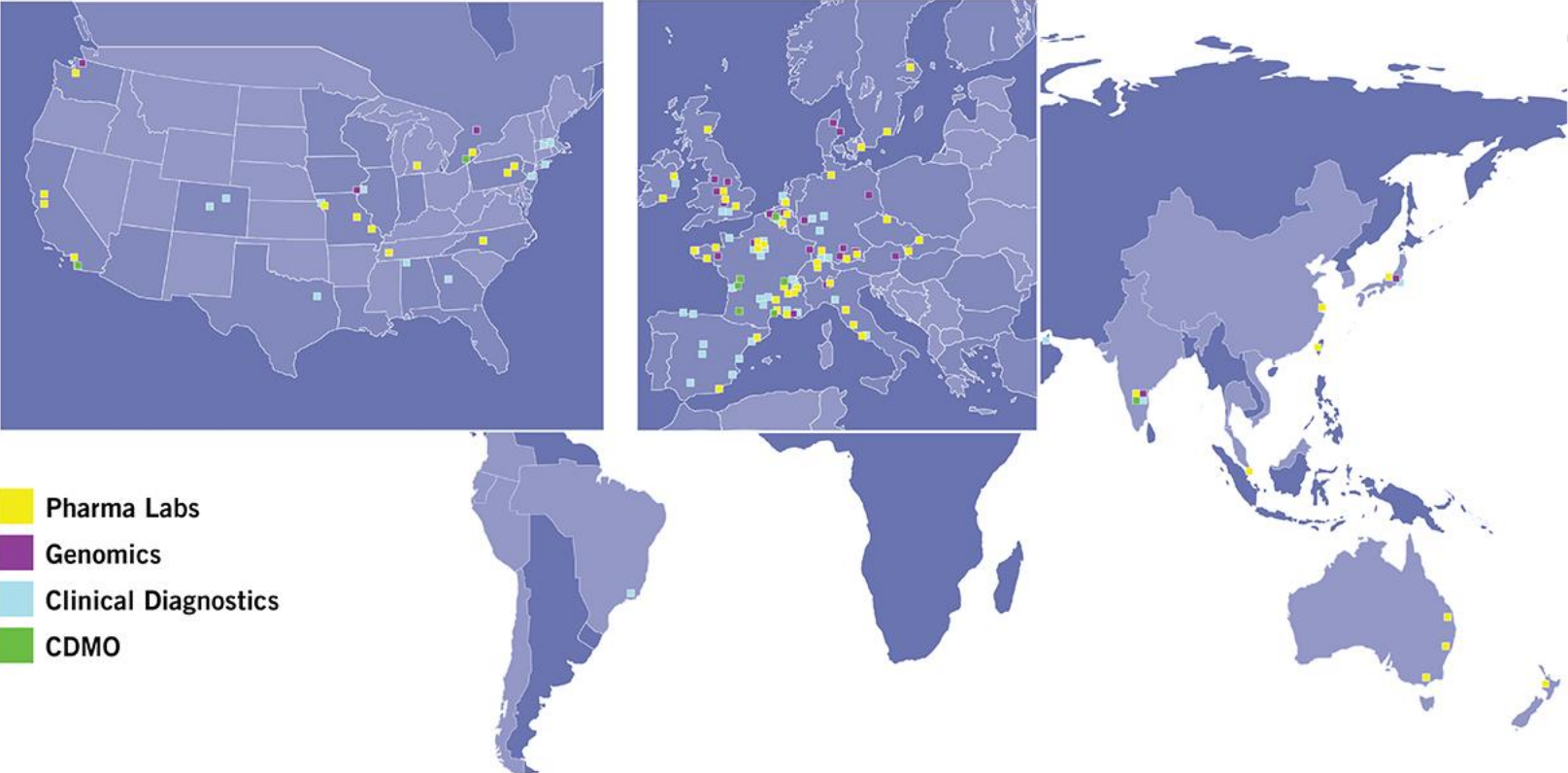
## Span the Complete Product Development Cycle

		File IND		File NDA, BLA, MAA	Launch Product
DISCOVERY		PRECLINICAL / EARLY DEVELOPMENT	CLINICAL RESEARCH & DEVELOPMENT	APPROVAL	COMMERCIAL
Lead Qualification Synthesize NME or New Biologic		Assess Safety and Biological Activity Pharmacology, Toxicity & DMPK	Assess Safety, Dosage & Efficacy in Humans Phase I, II and III Studies	Verify Safety, Effectiveness & Controls to Agency	Assess Long-Term Effectiveness (Phase IV Studies) Surveillance/Quality Control
<p><b>DISCOVERY:</b> Small Molecule and Biologic Screening and Characterization, Integrated Drug Discovery, Chemistry, in vitro Safety Pharmacology, Phenotypic Analysis, ADME-Tox, in vivo Models, Custom Assays and Product</p>					
PRODUCT	<p><b>PRECLINICAL / EARLY DEVELOPMENT:</b> Toxicology, Safety Pharmacology, Analytical Services</p>				
	<p><b>CDMO:</b> Drug Substance/API &amp; Drug Product Development &amp; Manufacturing for Biologics and Small Molecules</p>				
	<p><b>BIOPHARMA PRODUCT TESTING:</b> GLP, GMP, Stability, Quality Control, Microbiological Testing, Process Development</p>				
	<p><b>PSS:</b> Hiring, training and managing insourced scientists and related support staff at Client facilities.</p>				
Genomics: Next Generation Sequencing, Genotyping, Micro Arrays, Pharmacogenomics					
CLINICAL	<p><b>BIOANALYTICAL:</b> Bioavailability, PK/TK, Immunogenicity, NAb, Biomarkers, Bioequivalence</p>				
	<p><b>EARLY CLINICAL DEVELOPMENT:</b> Clinical Pharmacology, Global Clinical Trials, Biometrics</p>				
	<p><b>CENTRAL LABORATORY:</b> Safety, Biomarkers, Bioanalysis, Infectious Disease Services</p>				
	<p><b>SPECIALTY CLINICAL TRIAL LABORATORY:</b> Infectious Disease &amp; Molecular, Immune Response, Allergy/Hypersensitivity</p>				
	<p><b>ANATOMICAL PATHOLOGY:</b> Over 2,500 assays: [Molecular] Pathology, Histology, Cytology, FISH</p>				

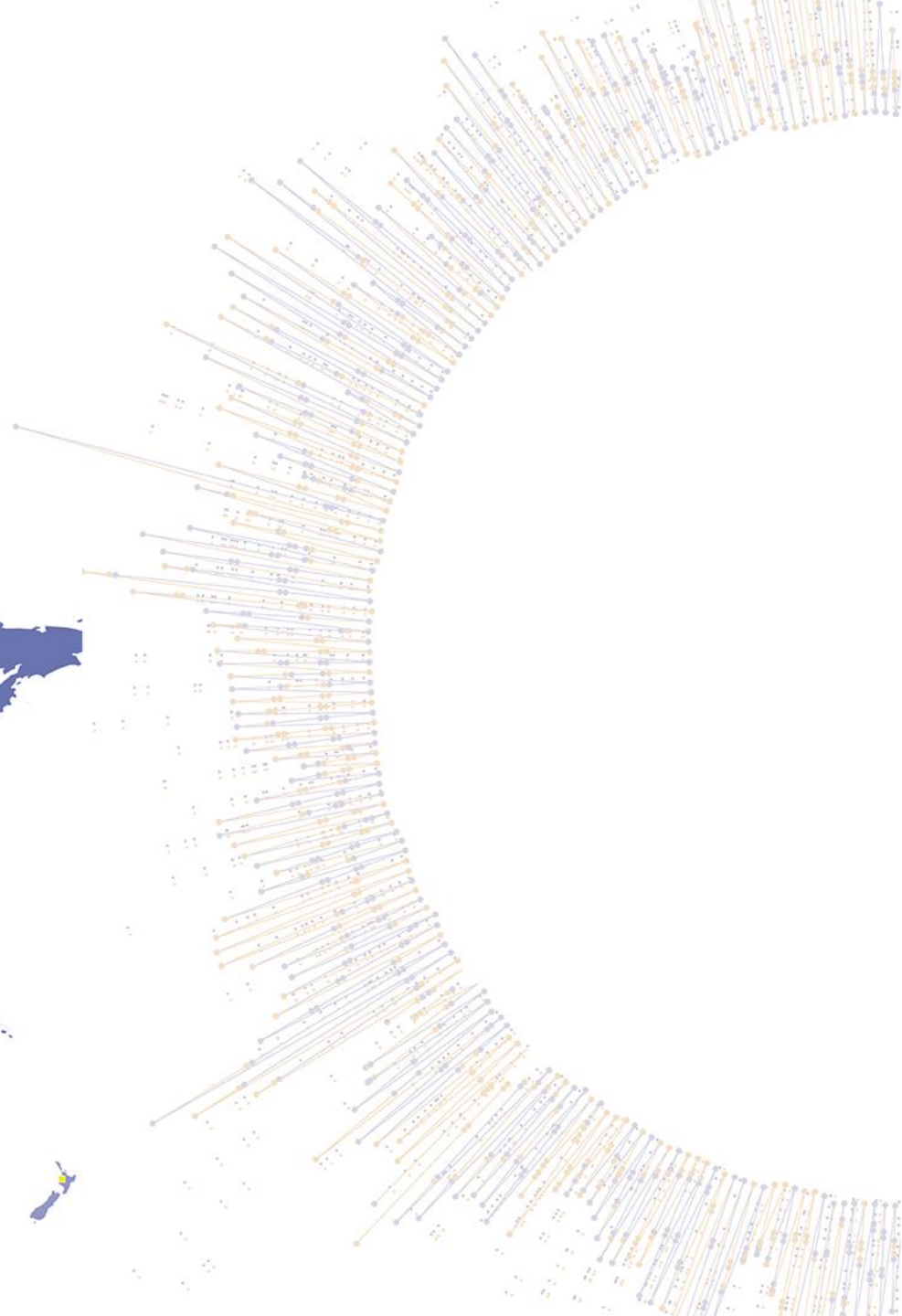


# Integrated Lab Performance and BioPharma Solutions From the Organization You Trust

From compound discovery and clinical research through manufacture and release of commercial product and post approval/marketing, Eurofins BioPharma Services provides seamless, end-to-end solutions to help clients progress through the drug development cycle through a single, experienced provider. Our integrated solutions deliver the most comprehensive range of state-of-the-art analytical technologies with an expansive geographic reach in order to support our clients' specialized testing needs and stringent quality and safety requirements around the world.



- Pharma Labs
- Genomics
- Clinical Diagnostics
- CDMO





BioPharma Services



**CRO** LEADERSHIP AWARDS 2022 CAPABILITIES  
**CRO** LEADERSHIP AWARDS 2022 COMPATIBILITY  
**CRO** LEADERSHIP AWARDS 2022 EXPERTISE  
**CRO** LEADERSHIP AWARDS 2022 RELIABILITY  
**CRO** LEADERSHIP AWARDS 2022 QUALITY





PRODUCT

**DISCOVERY**

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**DRUG DISCOVERY  
SERVICES**




**INTEGRATED DRUG  
DISCOVERY**



**DRUG DISCOVERY  
PRODUCTS**

## A Strong Foundation for Successful Drug Discovery

Eurofins Discovery offers you a complete, single-source solution for drug discovery products and services. We are rooted in the deep expertise and best-in-class offerings of 6 premier CROs: Cerep, DiscoverX, EMD Millipore Drug Discovery Solutions, Panlabs, Selcia Drug Discovery, and Villapharma.



Eurofins Discovery can optimize your discovery process - whether you need complete, end-to-end services, help with one or more stages, or the products for discovery work.

With over 600 scientists around the world, 50 patents, and 30 billion data points screened, you can rely on Eurofins Discovery to provide you with the deep resources needed for your success.

- **Standalone Services.** Offering the ability to support your projects on an as-needed basis across the drug discovery workflow, Eurofins Discovery offers you services for Medicinal Chemistry, Synthetic Chemistry, In Vitro Pharmacology, Safety & Efficacy, ADME & Toxicology, and Phenotypic Assays. In Vivo services are available through our partner lab, Pharmacology Discovery Services.
- **Integrated Drug Discovery.** The DiscoveryOne™ integrated drug discovery team works hand-in-hand as partners with you, integrating all Eurofins Discovery capabilities to accelerate delivery of preclinical candidates by utilizing our in-house project management and deep scientific expertise.

- **Products for Drug Discovery.** Eurofins DiscoverX, a Eurofins Discovery company, is the trusted product solutions provider that can accelerate your programs with confidence with qualified reagents, cell lines, and assays ready to run today. Eurofins DiscoverX develops and manufactures cutting-edge assays, stable cell lines, membrane preps, enzymes, and reagents for drug discovery and development.
- Eurofins Discovery provides global drug discovery support in USA, Europe, and Asia.



EUROFINS  
DISCOVERY



PRODUCT

## PRECLINICAL/EARLY DEVELOPMENT PRODUCT TESTING


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## Superior Service, Reliability and Results

The Federal Food and Drug Administration (FDA) is the agency responsible for protecting the public health by assuring the safety, effectiveness, quality, and scrutiny of human drugs, vaccines, and other biological products. Eurofins uses Partner Laboratories that understand the FDA's guidelines and requirements, so sponsors can be assured that testing will meet their specific requirements.



Eurofins Partner Laboratories are all leaders in providing the pharmaceutical industry with toxicology, safety, pharmacology, bioanalysis (PK/TK) and medical device testing services, using the latest in scientific techniques and instrumentation to evaluate drug candidates from discovery through early development.

Industry experts that have specialized in pharmaceutical and biopharmaceutical testing are being deployed. They excel at early discovery pharmacology and can evaluate pharmacological effects of drug candidates in all major therapeutic categories, with an emphasis on anti-infectives, inflammation/allergy, CNS disorders, and metabolic diseases. Clients can also be supported with efficacy testing and be further supported with robust historical control data to help further ensure the success of your product.

### Toxicology

- Product discovery and development, pre-clinical safety evaluations, product registration, product stewardship, regulatory compliance and risk assessment.
- GLP analytical chemistry support (dose concentration determination, method development and validation, stability evaluation) is also available as needed.

### Pharmacology

- More than 40 years of experience in performing a wide range of pharmacology test services to clients in the pharmaceutical and dietary supplement/nutraceutical industries.
- Pharmacology protocols in multiple therapeutic areas to help identify lead candidate selection and custom protocol development.
- Study designs: Screening, bioavailability, bioequivalence, tissue collection, metabolite collection.
- Analytical support: LC/MS, LC/UV, and ELISA (custom analytical protocols available).

### Analytical Services

- Bioanalytical and DMPK testing supporting discovery, preclinical and clinical studies providing method development, validation, and sample analysis in all biological matrices for both small and large molecule drug development.

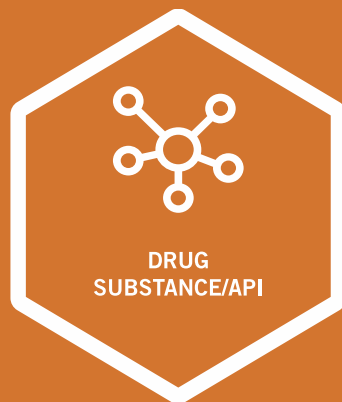


PRODUCT

**CDMO**

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Contact us at [cdmo@eurofins.com](mailto:cdmo@eurofins.com)





## Your Drug Development Partner

Eurofins CDMO provides a sustainable and flexible solution for pre-clinical and clinical development and manufacturing services for Drug Substance/API and Drug Products (Biologics and Small Molecules). Eurofins CDMO has state-of-the-art facilities in North America, Europe and India.

Science represents the foundation of our business and allows Eurofins CDMO to support small and major biopharmaceutical companies through a sustainable and flexible method to help them achieve their pre-clinical and clinical milestones on time.

We are experts in breakthrough technologies for highly potent compounds, poorly soluble drugs, lyophilisation processes and specific therapeutic areas (immunotherapies, orphan drugs, paediatric dosage forms, etc.) Involved in the earliest steps, our highly-qualified project management team will effectively communicate a complete drug development strategy to help meet your timelines.

Eurofins CDMO offers a vast range of services:

- Drug Substance/API development
- Solid State Research & Development
- Pre-Formulation and Formulation development
- GMP manufacturing
- Clinical packaging and logistics
- Project management and CMC RA

Operating under strict quality procedures, Eurofins CDMO is accredited through the FDA, EMA, ANSM, ANSES, FAMHP, PMDA, and Health Canada.

With more than 30 years of combined experience between all entities in preclinical and clinical development, our expert teams ensure your clinical trials achievements are:

- Supporting clients to move rapidly through the drug development value chain
- Performing complex formulation screening and development for sterile and non-sterile manufacturing
- Accelerating process development and scale-up under GMP compliance
- Supplying clinical trial material including packaging and logistics
- Complying with regulatory requirements throughout each stage of the development cycle with full CMC-RA support





PRODUCT

## BIOPHARMA PRODUCT TESTING

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## Largest Scope of Global Services. Sharpest Focus on Data Integrity.

With 35 testing facilities in 17 countries, Eurofins BioPharma Product Testing delivers the world's most comprehensive scope of harmonized GMP testing services and seamless regulatory acceptance.

Eurofins BioPharma Product Testing offers a unique global breadth of CMC testing services for the Bio/Pharmaceutical industry, including starting materials, process intermediates, drug substances, drug product, packaging, and manufacturing support through broad technical expertise in Biochemistry, Molecular & Cell Biology, Virology, Chemistry, and Microbiology.

- Method Establishment (Development, Validation, Transfer)
- Release Testing
- Stability Testing & Storage
- Characterization
- Residuals & Impurities Testing
- Raw Materials Testing
- Extractables & Leachables Testing
- Container & Package Testing
- Shipping Studies
- Viral Clearance & Viral Safety Testing
- Bioassay & Potency Testing
- Cell Banking Services
- Critical Reagents/Reference Standards Management
- Disinfectant Efficacy/Cleaning Validation Studies

- Environmental Monitoring
- Facility and Process Validation
- Organism Identification
- Clinical Trial Material Support
- Formulation Development/Testing
- Custom Synthesis & Radiolabeling

We offer clients the flexibility to manage testing programs more efficiently through a choice of three unique service models, including standard Fee for Service, our award-winning Professional Scientific Services® (PSS) Insourcing Solutions, and Full-Time-Equivalent (FTE) service models.

BIOPHARMA  
PRODUCT  
TESTING



PRODUCT

## PROFESSIONAL SCIENTIFIC SERVICES (PSS) INSOURCING SOLUTIONS

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AWARD-WINNING  
INSOURCING SOLUTIONS



2,000 PSS EMPLOYEES  
WORLDWIDE




70 CLIENT LOCATIONS  
IN 20 COUNTRIES



## When you have the workload, but not the workforce.

PSS Insourcing Solutions® provides laboratory management services for Bio/Pharmaceutical companies who face workload/workforce challenges and require testing to remain at their facility. We place our people at our client's facility dedicated to running and managing their laboratory services while eliminating headcount, co-employment, and project-management worries.



Founded under Eurofins Lancaster Laboratories, PSS infuses our 58-year track record of scientific and laboratory operations expertise, as well as HR and great place to work best practices to recruit, hire, train, and manage highly qualified scientists to perform laboratory services at our client's site, using their quality systems and equipment. Our teams will even help set up the laboratory and validate equipment according to the client's SOPs and laboratory practices as needed.

We have proven success providing dedicated teams for a variety of technical disciplines that span the drug development pipeline, providing:

- The security of keeping your projects at your facility.
- Solutions to potential co-employment issues and challenges associated with staff augmentation.
- Metrics to demonstrate productivities, efficiencies, and cost savings.
- Lean laboratory best practices and training to save time, eliminate waste, and ultimately bring cost savings to our PSS clients.
- A resource for technical expertise and support through laboratory staff at our network of global facilities.

We know how to find great people and take great care of them, so they in turn will take great care of our clients.

CLINICAL


GENOMICS

Visit us at [eurofinsgenomics.com](http://eurofinsgenomics.com) Contact us at [pharmacogenetics-eu@eurofins.com](mailto:pharmacogenetics-eu@eurofins.com)



## Fast-track Your Path

Eurofins Genomics provides solutions to your needs: from standardized products like oligonucleotides, Sanger sequencing and gene synthesis to highly customized project based services. We fast-track your path to the next blockbuster drug using next generation sequencing (NGS), microarrays and qPCR/dPCR with rapid turnaround times as well as industry leading quality.

- 
- As the largest microarray service provider in Europe for Illumina and ThermoFisher arrays we are able to offer you a broad portfolio of services with excellent turnaround times. The fact that we were the first service provider for ThermoFisher arrays in Europe distinguishes us and emphasizes our capabilities using this technology.
  - Your research benefits from our extensive experience gained over a broad variety of successful genotyping and qPCR studies. We recently extended our portfolio offering now also dPCR analyses to detect and quantify gene therapy viral vectors.
  - We provide you with high-quality NGS services made in Germany. Our NGS laboratory in Germany started already in 2006 as the first European service provider in Europe. Building on this foundation we have been at the forefront of technical advancements and applied these technologies for very different scientific requests including testing for clinical trials.
  - We produce high-quality oligonucleotides tailored for your needs in BioPharma applications using exclusive synthesis technology combining low error rates with excellent turnaround times. Using this technology we can also offer the synthesis of Genes and GeneStrands with optimized rates accredited according to ISO 13485.
  - With four independent, global laboratories we ensure redundant and foremost reliable production of your ordered services and products.
  - We provide you GCLP compliant services for NGS, microarrays as well as for various Applied Genomics projects. We further offer a broad spectrum of different analytical services accredited according to ISO 17025 requirements.





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**BIOANALYTICAL  
SERVICES**

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## Biologics Done Right

Eurofins is a leading supplier of bioanalysis and DMPK solutions, with cutting-edge scientific expertise. We support discovery, preclinical and clinical studies providing method development, validation, and sample analysis in all biological matrices for both small and large molecule drug development. We offer a comprehensive range of PK/TK, ADME, ADA, NAb, biomarker assays and sample analysis to all sponsors in the world's pharmaceutical and biopharmaceutical landscape.

We have a mission to support our clients with high quality Bioanalysis and DMPK results in both pre-clinical and clinical development. Our sole focus is providing the precision and accuracy in the data that our clients need for decision making, IND filings and product registrations in both small and large molecules, and biomarkers.

Eurofins Bioanalytical Services laboratories are at the forefront of novel approaches to overcome the most complex assay challenges and demonstrate industry leadership in developing, optimizing, validating and performing immunoassays and LC/MS/MS bioanalysis on human and animal specimens. We offer trusted bioanalytical solutions to support studies from preclinical non-GLP to IND-enabling Toxicity studies to multi-national Phase III clinical trials. We can take your drug from research through development to regulatory submission.

We offer:

- Scientific expertise supporting the widest scope in clinical trials with small and large molecule bioanalysis for PK/TK, ADA and cell-based NAb. Our services also include PK calculations and interpretation, bioequivalence studies, and biomarker assays.
- State-of-the-art laboratory facilities in the USA and France providing diverse platforms and technologies including LC-MS/MS and ELISA to address increasingly demanding client specifications.
- In-house development of small molecule assays, ELISA and ECL development, creation and analysis of antibody-drug conjugates.
- Dermal absorption studies [in vitro/in vivo]
- Advice from a highly qualified team, adaptability for all study designs, flexibility in timelines.
- The benefit of our experience with biotechs as well as with mid and large size pharma companies with an international recognition for the quality of our services.

BIOANALYTICAL  
SERVICES



CLINICAL  
**EARLY CLINICAL  
DEVELOPMENT**

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**DOCUMENT  
DEVELOPMENT**



**CLINICAL  
INVESTIGATIONS**




**DATA COLLECTION/  
MANAGEMENT**



## Early Drug Development Experts

Eurofins Optimed is the clinical competence center of the group, providing integrated solutions for the global management of international clinical trials, to the pharma, biotech, and medical device industries.



Focused on early clinical development, our experience of more than 1,000 trials conducted since our creation establishes us as a reliable partner. We are able to provide you with GCP services in any therapeutic field thanks to our experienced team of experts and our large network of Key Opinion Leaders.

As every clinical project is specific, we offer tailor-made solutions among the following activities:

- Study document development: protocol, ICF, e-CRF, diaries, IMPD
- Regulatory support and submissions in Europe and in the USA
- Clinical Investigations: in our Clinical Pharmacology Unit (France – 60 beds) or through our network of Investigators within Europe and the USA
- Support services: feasibility studies (site identification and qualification), project management, site coordination, monitoring
- Data collection and analysis: data management, statistics, e-CRF, medical writing, ePro

Our unified e-clinical platform spans clinical operations and clinical data management. It provides a multi-tenant cloud and mobile-based workspace for all drug development activity. This system provides users with complete clinical trial transparency, ensures data consolidation with a single database and offers advanced reporting including integrated dashboards, KPIs, standard reports and ad hoc reports.



CLINICAL

# CENTRAL LABORATORY

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CLINICAL LABORATORY  
TESTING




FIT-FOR-PURPOSE  
BIOMARKERS



KITS MANUFACTURING  
& DISTRIBUTION

## Results That Matter

Reliable, high quality laboratory data is pivotal to the success of clinical trials. It's the RESULTS THAT MATTER. We are dedicated to providing the most cost effective and efficient testing solutions to pharmaceutical and biotech companies, and CROs alike.



At Eurofins Central Laboratory, we are the End-to-End solution to the BioPharma industry! As a dedicated Laboratory CRO, we go above and beyond to provide an array of services to ensure that any clinical trial sample is collected, transported, managed, analyzed, reported and stored to meet the objectives and purpose of each study. Deploying our 4 standardized, wholly-owned global locations in USA, the Netherlands, Singapore and China, we provide CAP/CLIA certified analytical services in both a GCP and GCLP environment. This allows us to combine safety and efficacy analysis with Biomarker Services embedded within one laboratory, introducing cost efficiencies into Sponsor study budgets, and increasing specimen integrity by reducing unnecessary transport. With Eurofins Central Laboratory acting as the hub, in a hub and spokes model, Sponsors will also have access to the extensive Testing Portfolio available within the Eurofins BioPharma Services Group.

What differentiates Eurofins Central Laboratory from the rest? Innovation. Whether that is our specimen visibility tool, EzRF (web based requisition), our home based, patient specimen collection kits or our mobile laboratory technician service for standardized CAP certified on-site analysis of rapid analytical TAT requirements (PBMC, semen analysis, virology specimen processing), Eurofins Central Laboratory is your analytical solution for Phase 1 to 4 clinical trials.

With over 20 years of experience in kit packing and distribution, Eurofins Central Laboratory offers Kit Packing and Distribution Services using wholly owned and fully harmonized Kit Packing facilities in the USA, Europe and China. Building on a proven track record of building and distributing study and visit-specific specimen collection kits in support of Clinical Trials, we also provide specimen collection kits for Commercial DNA Testing, Clinical Diagnostics, Clinical Monitoring Programs and Post Marketing Surveillance.







CLINICAL

## SPECIALTY CLINICAL TRIAL LABORATORY


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Contact us at [info@viracor-eurofins.com](mailto:info@viracor-eurofins.com)



## Get Results Faster When it Matters Most

Viracor Eurofins is a specialty clinical development laboratory, offering complex/esoteric testing and assay development, to help advance your Phase 1-4 clinical trials through trusted partnership, scientific excellence and exceptional service.



For more than 30 years, Viracor has been dedicated to helping clients by providing high quality, accurate results to evaluate the effects of drug candidates across all major therapeutic categories. We offer broad experience in molecular infectious disease testing, vaccine safety/efficacy assessment, immunogenicity, cell-based assays, allergy/hypersensitivity, and biomarker analysis. Our validated test list includes more than 2800 assays, with new custom assays developed on a continual basis, in response to client needs.

### Agility

Viracor Eurofins leverages over 16 different technology platforms, and accepts a broad range of specimen types, widening our capabilities and enabling us to customize testing to your trial's exact needs, together with the scalability to manage trials of any size. We are also a CAP accredited/CLIA certified laboratory and we adhere to GCP guidelines.

### Speed

Our high-throughput laboratory can support your clinical trials with the capacity to process large sample volumes quickly, support studies with short set up timelines and provide rapid turnaround times. Our project managers and scientists act as part of your team – going above and beyond to get you the results you need when you need them.

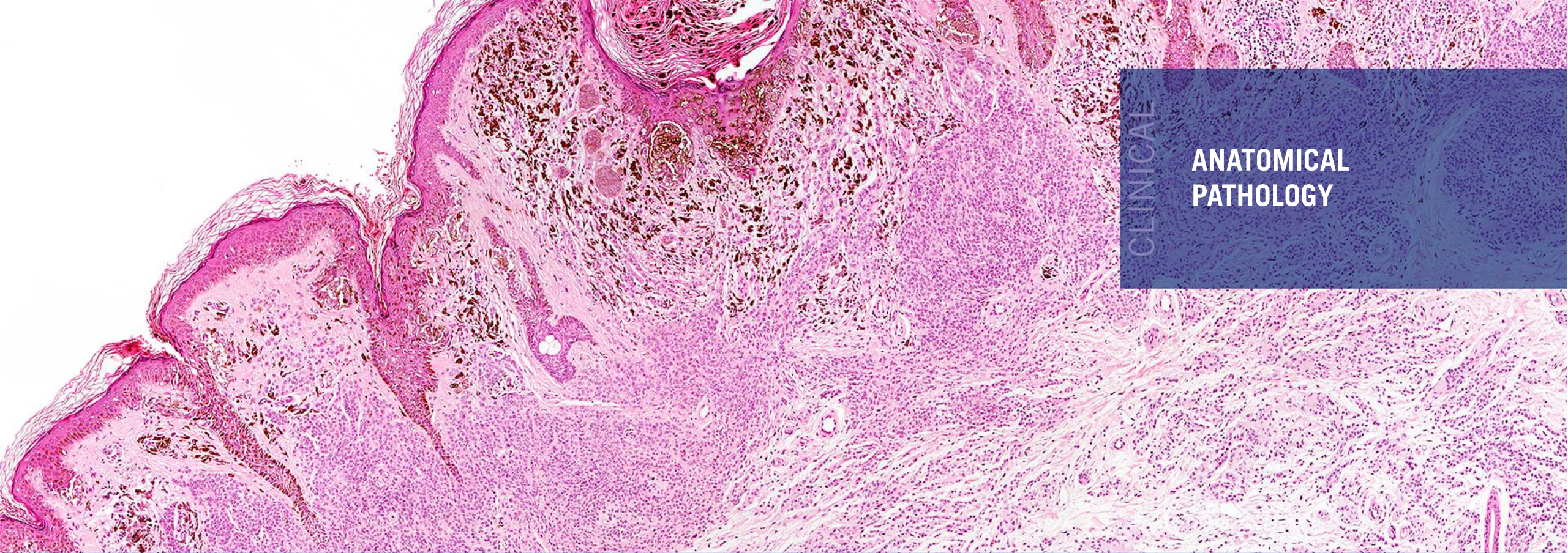
### Expertise

We're driven to partner with you to solve difficult scientific problems, complementing your strategies with expertise in complex method development on multiple technology platforms, validation, and technology transfer; to accelerate your compound, vaccine, gene/immuno-therapy or other biological from bench to market. Our Research & Development team serves as an extension of your laboratory, with unique skills in technology platform selection and protocol design. Clients can expect exceptional service and proactive communication from a dedicated project manager, who will ensure alignment on project requirements, timelines and budgets.



VIRACOR  
EUROFINS  
BIOPHARMA





CLINICAL

# ANATOMICAL PATHOLOGY

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**MULTIPLE  
SPECIALTIES**



**STANDARDIZED  
RESULTS**



**20+ YEARS  
SCIENTIFIC EXPERIENCE**



## Specialized Medical Pathology

The deployment of pathology testing has become increasingly important in safety, vaccine and oncology trials. Pathology testing is facing similar challenges as central laboratory testing; large sample numbers distributed over many locations, a need for expert global logistics support to maintain specimen integrity, quick turnaround time of results and the necessity for globally combinable data.

With a keen eye on the specifics of a clinical trial, Eurofins Biomnis offers anatomic, clinical and molecular pathology services to assess traditional clinical-pathological factors as well as the molecular biological features of a given tumor to support safety, vaccine and oncology trials.

Eurofins Biomnis focuses mainly on specialised pathology testing, which requires highly skilled expertise, and which cannot be performed in routine private or hospital-based laboratories. Eurofins Biomnis specialises in all areas of pathology and testing is performed using the most recent and cutting-edge techniques, which necessitate complex calibrations and validations, highly qualified experts and sophisticated equipment.

- Surgical pathology
- Tumor confirmation and classification
- Pathology reads for efficacy
- Slide preparation and preservation
- Histology
- Cytology
- Molecular pathology
- FISH

The air we breathe, the food we eat, the water we drink, the everyday products we use, the diagnostic techniques, treatments and medicines we rely on when we are unwell – so often we take them for granted. As we go about our daily lives, many of us scarcely notice the complex processes, scientific endeavor and rigorous testing that keep us, and the environment around us, safe and well.

As a world leader and innovator in analytical testing, Eurofins is the Quiet Hero that stands between you and the hazards of an ever-changing, highly complex world.



**BioPharma Services**