

One Goal - Five Labs

Over the years Eurofins has built up a strong network of laboratories to deliver the most comprehensive service in biopharma product testing. We offer the right support for your specific product at one of our laboratories or even at your own facility.



At Eurofins BioPharma Product Testing in Germany and Switzerland we are providing quality testing services for the largest pharmaceutical and biopharmaceutical companies in the world under GMP, GcP and GLP conditions, supporting you throughout all phases of the drug development process.



With our partner BSL BIOSERVICE we complete our service spectrum, offering *in vivo* safety and activity testing services for your individual product, including preclinical assessment, pharmacology and toxicology studies.



Eurofins Professional Scientific Service® (PSS) is a global, award-winning insourcing solution that places our people at your site dedicated to running and managing your laboratory services while eliminating headcount, co-employment and project-management worries.

Eurofins BioPharma Product Testing Munich GmbH

Behringstraße 6/8
D-82152 Planegg / Munich
Phone +49 89 89 96 50 0
info-munich@eurofins.com

Eurofins BioPharma Product Testing Hamburg GmbH

Grossmoorbogen 25
D-21079 Hamburg
Phone +49 40 49 29 45 90 0
Pharma-Hamburg@eurofins.de

Eurofins BioPharma Product Testing Switzerland AG

Parkstraße 10
CH-5012 Schönenwerd
Phone +41 62 85 87 12 9
BioPharma@eurofins.ch

Eurofins Professional Scientific Services Germany GmbH

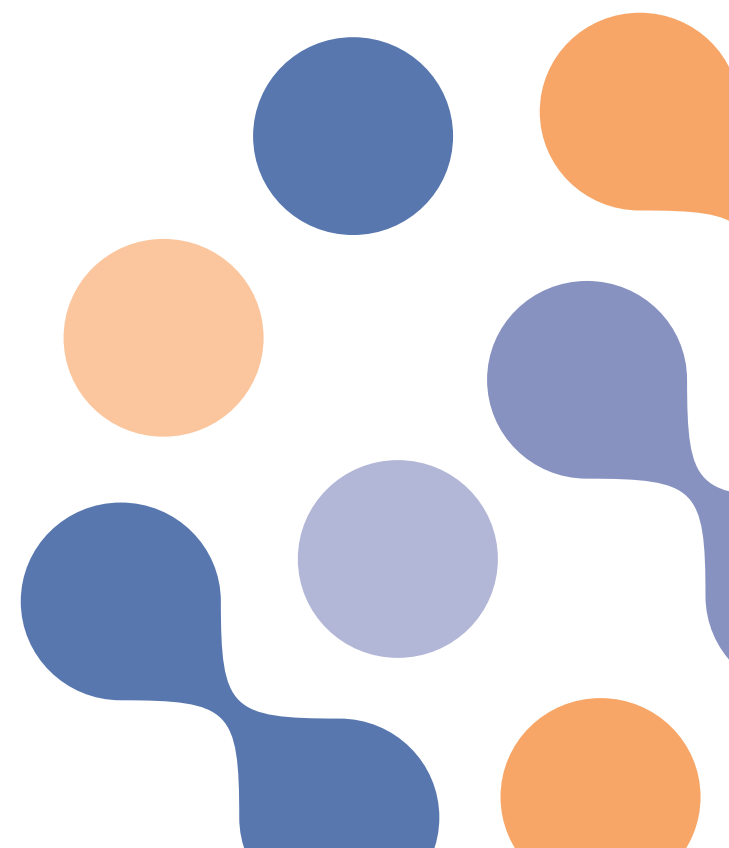
Behringstraße 6/8
D-82152 Planegg / Munich
Phone +49 89 28 85 48 8-0
info-munich@eurofins.com

BSL BIOSERVICE

Scientific Laboratories Munich GmbH
Behringstraße 6-8
D-82152 Planegg / Munich
Phone +49 89 89 99 74 9-0
info@bioservice.com



BioPharma
Product Testing



www.eurofins.com/biopharma



Your Lab of Choice for
BioPharma Product Testing

Eurofins BioPharma Product Testing

Comprehensive Testing Services for (Bio-)Pharmaceuticals

Eurofins BioPharma Product Testing is the largest network of harmonized bio/pharmaceutical GMP product testing laboratories worldwide providing comprehensive laboratory services for the world's largest pharmaceutical, biopharmaceutical and medical device companies.

Our service offerings are fully comprehensive and include testing of drug substance, final product, intermediates, and starting materials for both small and large molecule drug products.

We give clients the flexibility to choose from three service models to meet specific project needs, including our Professional Scientific Services® (PSS) for insourcing solutions.

Our laboratories offer a broad range of methodologies under GMP, GLP and GcP authorization, ISO 17025 accreditation and ISO 9000 certification and all analysis are performed according to known Pharmacopeias as well as specific customer methods.

With a global capacity of more than 92,000 square meters and facilities all around the world, our network of GMP laboratories operates under the same strict quality procedures, LIMS and centralized billing system across 28 locations worldwide.



Our Services at A Glance

Three Different Service Models

- Traditional Fee-for-Service
- FTEs working exclusively for one client
- PSS (Professional Scientific Services)

Method Validation (GMP)

- Method transfer
- Method verification
- Method validation according to ICH Q2 guidelines

Pharmaceutical Release & Stability Testing (GMP) for Small Molecules and Biologics

- Identity testing
- Activity testing
- Impurity testing
- Analysis of physical properties

Bioanalytical Studies (GLP, GcP)

- Biomarker analysis
- Immunogenicity testing
- Pharmacokinetic (PK) assessment services
- Cellular immunology testing
- PBMC services

Pharmacology (GLP)

- *In vivo* proof of concept and efficacy studies
- Pharmacodynamics
- Pharmacokinetics and toxicokinetics
- Safety pharmacology

Preclinical Assessment (GLP)

- Metabolism
- Drug Interaction
- Permeability and transport
- ADME *in vivo*

Toxicology (GLP)

- Cytotoxicity, phototoxicity *in vitro*
- Acute toxicity
- Subacute, subchronic, chronic toxicity
- Carcinogenicity
- Developmental and reproductive toxicity (DART)
- Sensitization
- Genetic toxicology
- Immunotoxicity
- Immunogenicity

Active Ingredients and Excipients

- Small Molecule Testing
- 5-day Express Service

Analysis of Persistent Organic Pollutants

- Dioxins
- PCBs
- BFRs
- PAHs

Heavy Metals

- Limit test
- Analysis with GAAS, FAAS or Mercury-Analyzer
- Analysis according to EP, USP or ICH Q3D by ICP-MS

Herbals

- Sampling
- Testing of full Monograph
- Mycotoxins (aflatoxins and ochratoxins)
- Heavy metals
- Pesticides
- Pyrrolizidine alkaloids
- Microbiology

Extractables and Leachables Testing

- Extraction
- Simulation
- Monitoring

Pharmaceutical-grade Glycerol

- Examination according to monographs
- Heavy metals screening using ICP-MS
- Viscosities

Microbiology

- Non-sterile product testing
- Sterility testing
- Endotoxins determination
- Facility Monitoring

Bioassay and Potency Testing

- Biological binding assays
- Cell based bioassays (*in vitro*)
- *In vivo* potency assays