eurofins

BioPharma
Product Testing

The largest global network of harmonised bio/pharmaceutical GMP product testing laboratories


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ABOUT
EUROFINS BIOPHARMA PRODUCT TESTING

We provide the industry's largest scope of global CMC services with a focus on data integrity

From starting materials to finished product testing, and preclinical and post-commercialisation, Eurofins BioPharma Product Testing delivers the most comprehensive scope of harmonised GMP testing services and seamless regulatory acceptance across the globe.

As we have grown to become the world's largest network of GMP product testing labs, **with 46 facilities in over 20 countries**, we continue to uphold our founding promise of personal service and impeccable quality.

When patients await your products, choose the team that provides complete capabilities and rigorous quality systems you can trust.

World's Largest Network of Harmonised GMP Product Testing Labs

Our globally-harmonised approach to laboratory services ensures the same level of service at all of our facilities

46 BioPharma sites

112 PSS Insourcing Solutions® sites

22 Medical Device sites

North America
8
3
66

Europe
45
30
17

South America
1

Asia/Pacific
7
2
1

Bespoke IT Solutions

Our laboratories meet all of your GMP testing needs by utilising in-house developed LIMS, ELN, Document Management, and Client Portal systems.

Global Quality Policy Manual Adherence

We operate under the Global Quality Policy Manual and utilise the CAPA/Exceptions Management System.

Over 400 Stability Chambers

Our 400 stability chambers encompass over 413,900 ft^3/ 12,200 m^3 to accommodate all ICH-VICH conditions, including photostability, Atex and LN2 conditions, as well as custom conditions based on client requests.

Expansive Industry Leading Biopharmaceutical Services

With controlled-access tissue culture and virology, biochemistry, molecular and cell biology laboratories, our laboratories are equipped for a wide variety of assays, including qPCR and cell-based potency assays, as well as ISO 7, A/B cell banking suites and BSL 2 and BSL 3 laboratories.

World-Class Chemistry

Featuring state-of-the-art mass spectrometry and chromatographic capabilities in support of small molecule finished products, APIs, and the world's largest raw material capacity.

More than 200 State-of-the-Art Microbiology Laboratory Modules

Our laboratory modules total more than 150,000 ft^2 / 15,000 m^2, with multiple sterility suites, including clean rooms and isolator technology.

Choose from a comprehensive range of biologics, cell and gene therapy, nucleic acid therapy, and small molecule testing services

With industry-leading testing capabilities, renowned scientific expertise, and state-of-the-art instrumentation, Eurofins BioPharma Product Testing can support the development and validation of virtually any test for your starting materials, API/drug substance, intermediates, drug products and packaging under GLP and cGMP guidelines.

Whether you need expert testing consultation, method development, validation or protocol design, Eurofins BioPharma Product Testing supports all functional areas of bio/pharmaceutical drug development with unmatched technical expertise in Biochemistry, Chemistry, Microbiology, Molecular & Cell Biology and Virology.

Why Choose Eurofins BioPharma Product Testing?

An industry innovator

For more than 60 years, we've built a reputation as a scientific leader working with nearly every type of molecule, formulation, therapeutic area and comparative product.

Meeting global reporting requirements

Our history of strict compliance and routine audits by clients and regulatory agencies such as FDA, EMA, IMB, PMDA and TGA, gives us the expertise for your global reporting needs.

Simplifying complexity

Your dedicated project manager serves as a single point of contact with knowledge of all aspects of your project requirements, offering consistent communications and timely project status updates.

Harmonised methodologies

We offer a broad range of harmonised methodologies under GMP regulations and ISO 17025, ISO 9000 and ISO 14001 certifications, and analyses are performed according to United States Pharmacopeia (USP), European Pharmacopeia (Ph.Eur), British Pharmacopeia (BP) and Japanese Pharmacopeia (JP), as well as Eurofins developed and customer specific methods.

Global Services

We're the #1 testing resource offering the most comprehensive services you need to get your product to market.

- Method Establishment (Development, Feasibility, Optimisation, Verification, Qualification, Validation, Transfer)
- Characterisation
- Raw Materials Testing
- Critical Reagents/Reference Standards Management
- Residual Impurities Testing
- Release Testing
- Sterile (Compendial & Rapid) and Non-sterile Microbiology Testing
- Disinfectant Efficacy/Cleaning Validation Studies
- Environmental Monitoring
- Facility and Process Validation
- Microorganism Identification
- Stability Testing & Storage
- Cell Bank Manufacturing & Characterisation
- Viral Clearance & Viral Safety Testing
- Bioassay & Potency Testing
- Extractables & Leachables Testing
- Container, Package & Closure Integrity Testing
- Functional Testing & Failure Analysis
- Shipping Studies
- Formulation Development/Testing
- Custom Synthesis & Radiolabeling
- Sterile Fill/Finish Manufacturing
- Clinical Trial Material Support
- Scientific Consulting
- Human Factors Testing
- Annex 1 compliance

Flexible Service Delivery Models

Eurofins BioPharma Product Testing helps you manage your drug development programs more efficiently through your choice of three unique service models.

In addition to the most commonly used service model in the industry, Fee-for-Service, we offer additional options to allow you to choose the best, most cost-effective service solution for your project goals at any of our global facilities, such as:

Full-Time Equivalent (FTE)

Our FTE program provides you with dedicated, full-time employees to work on your projects at our GMP facilities. Managed by us, your dedicated FTE employees use our infrastructure, equipment, and consumables to meet your project testing needs.

To ensure maximum team performance and drive optimised cost benefit, our FTE program offers:

- Secured capacity that delivers enhanced performance and productivity derived from client specific product and method familiarity.
- Dedicated and client accessible technical team leaders that manage your projects and direct the priorities of the team which provides nimble scheduling and no rush surcharges.
- Option to integrate our operations into your IT platforms, such as LIMS, ELN, or chromatography systems.
- 24/7 access to data and reports through our secure online portal, LabAccess℠, including options for automated LIMS to LIMS transfer and Online Ordering.
- Detailed monthly utilisation reports, including customised metric reports on FTE team productivity and quality performance.
- Simplified and customised monthly invoicing.

PSS Insourcing Solutions®

When you have the facilities, the workload, but not the workforce, PSS® Insourcing Solutions places our full-time scientists and technical support personnel, managed by us, at your facility to provide a long-term and cost-effective way to meet your laboratory testing needs with administration, legal, management and leadership all taken care of, PSS® makes life easier.

With more than 3,000 employees serving customers at more than 100 different client sites worldwide, our innovative, award-winning PSS® program offers:

- The convenience of keeping your projects in your facility.
- Scientific expertise from early phases to finished product testing, from routine to complex projects
- Compliance with the highest quality standards (GLP, GMP, ISO).
- A solution to turnover rate and other issues caused by traditional temporary staffing programs.
- Full compliance with each country's employment regulations (including co-employment).
- LEAN Project Support and Management, as well as LEAN Laboratory Design and Validation.
- Cost-savings and operational excellence metrics.
- Flexibility to increase or decrease the size of project teams over time based on long-term project needs.

Harmonisation Drives Quality and Data Integrity

We take rigorous steps to ensure our systems and quality program meet global regulatory requirements. We operate worldwide under the same quality control and operating procedures, delivering standardisation and implementation of best practices.

In order to achieve our stringent quality metrics goals and provide data you can trust, we continue to invest significantly in extremely precise instrumentation and supporting systems, including our proprietary LIMS platform, eLIMS-BPT, and Electronic Laboratory Notebooks (ELN) platforms, as well as our secure online portal, LabAccess.

These critical systems provide seamless testing, standardised deliverables and convenient access to data for our clients worldwide. We have a global team of IT engineers, testers, and analysts dedicated to developing and enhancing these systems.

LabAccess℠

A pioneer in providing innovative online data access, our secure portal, LabAccess is one of the most trusted, comprehensive and user-friendly data management tools in the industry. Saving you valuable time, our platform offers maximum efficiency and 24/7 access to project data, including:

- Current and past projects
- Sample information
- Analysts' notebooks
- Chromatograms
- Lists of tests and results
- Exporting of results
- Electronic signatures
- Preliminary data reports
- Raw data PDFs
- Stability study management tool with links between stability samples and corresponding testing data and results
- Secure automated exchange of data with client IT systems
- Certificates of Analysis
- Online ordering and seamless re-ordering
- Quotes, purchase orders and invoices

eLIMS-BPT

Our primary operating software, eLIMS-BPT, is a proprietary platform developed in-house to ensure a seamless transfer of information through our laboratories.

From quotation to electronic sample submission forms, to final reports and all documentation in between, this robust platform is the foundation for how we do business.

Electronic Laboratory Notebooks

Of paramount importance, our Electronic Laboratory Notebooks (ELN) system provides a harmonised process for recording and reviewing analytical data. ELN maintains compliance, ensures consistency from experiment to experiment, and reduces the time needed for the entry, review, and approval of experiments.

The key benefits to using ELN across our organisation include a significant reduction in exceptions, harmonisation of procedures, efficiency of data entry and access, and the ability to programmatically enforce procedures and business rules.

www.Eurofins.com/BPT

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service

Full-Time-Equivalent

PSS Insourcing Solutions®

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