eurofins | BioPharma Product Testing

Largest scope of global services
Sharpest focus on data integrity

From Starting Materials through Finished Product Testing, Eurofins BioPharma Product Testing's 39 facilities in 19 countries deliver the world's most comprehensive scope of harmonized GMP testing services and seamless regulatory acceptance.

As we have grown to become the world's largest network of GMP product testing labs, we continue to uphold our founding promise of personal service and impeccable quality.

When the world awaits your product, choose the lab that provides complete capabilities and rigorous quality systems you can trust.


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The most comprehensive range of large and small molecule testing services available, worldwide

With industry-leading testing capabilities, 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 material, API, bulk product, finished product, intermediate 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.

Global Services

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

Why Choose Eurofins BioPharma Product Testing?

- As a pioneer in Microbiology, Chemistry, Biochemistry and Biosafety testing for more than 30 years, Eurofins BioPharma Product Testing has a proven track record working with virtually every type of molecule, formulation, therapeutic area and comparator product.

- Our laboratories offer a broad range of harmonized methodologies under GMP authorization, ISO 17025 accreditation and ISO 9000 certification and analyses are performed according to European and British Pharmacopeia (EP), United States Pharmacopeia (USP) and Japanese Pharmacopeia (JP), as well as Eurofins developed and customer specific methods.

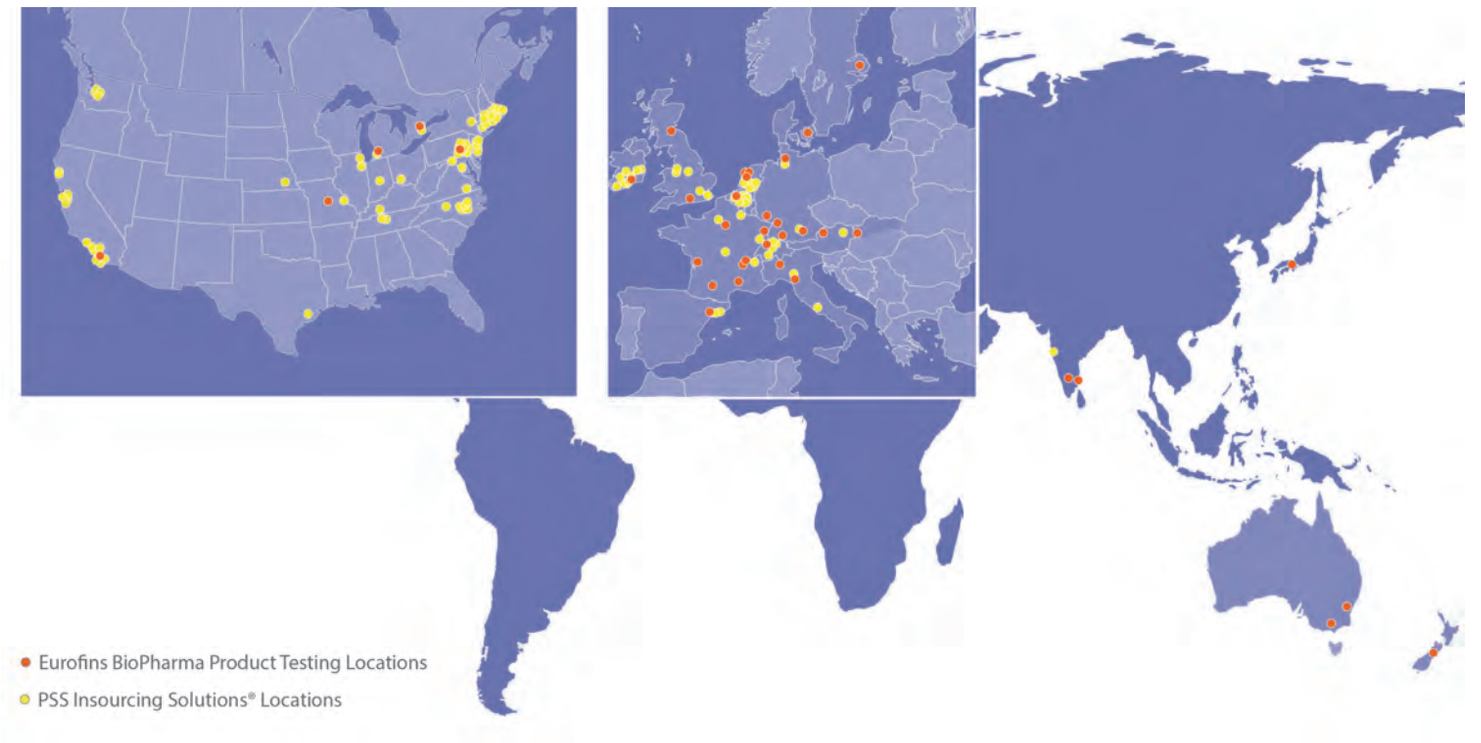
- Our history of strict compliance and routine audits by clients and regulatory agencies such as FDA, EMA, IMB, PMDA and TGA, gives us the expertise to meet the global reporting needs of our customers.

- We provide consistent communication and thorough knowledge of your project status through a dedicated project manager who serves as your single point of contact and works with all aspects of your project.

The largest international presence while delivering a true local lab experience

With more than 7,300 employees and a global capacity of 2,100,000 ft^2 / 200,000 m^2 and 39 facilities worldwide, our network of GMP laboratories delivers a harmonized approach to laboratory services to ensure that all global customers receive the same level of service at any of our facilities.

The equipment, expertise and procedures in our laboratories meet all of your GMP testing needs using the same LIMS, strict quality procedures and centralized billing system across all locations. All of our laboratories also operate under the same Global Quality Policy Manual and utilize the same CAPA/Exceptions Management System and Document Management System.



Eurofins BioPharma Product Testing Offers

- Chemistry and biochemistry laboratories that include a full array of mass spectrometry, electrophoretic and chromatographic capabilities.
- Expansive biopharmaceutical services departments that include controlled-access tissue culture and virology laboratories, molecular and cell biology laboratories equipped for a wide variety of assays, including qPCR assays and cell-based potency assays, as well as ISO 7, A/B cell banking suites and BSL 2 labs.
- More than 200 state-of-the-art microbiology laboratory modules, totaling more than 150,000 ft^2 / 15,000 m^2, with multiple sterility suites, including clean rooms and isolator technology.
- 400 stability chambers encompassing over 413,900 ft^3 / 11,700 m^3 to accommodate all ICH conditions, including photostability and LN2 conditions, as well as custom conditions based on client requests.

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 method 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.

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 the overall cost benefit of this approach, our FTE program offers:

- The same level of quality, performance and productivity as our traditional Fee-for-Service offerings.
- Team leaders to manage your projects, direct the priorities of the team and even integrate our operations with client systems/SOPs.
- Detailed monthly utilization reports, including customized metric reports on FTE team productivity and quality performance.
- Option to integrate into client IT platforms, such as LIMS.
- 24/7 access to data and reports through our secure online portal, LabAccess.com.
- Four unique FTE program options designed to meet the testing needs of virtually any project.

PSS Insourcing Solutions® (PSS)

Our PSS Insourcing Solution places full-time scientists and technical support personnel, managed by Eurofins BioPharma Product Testing, directly **at your facility** to provide a long-term and cost-effective way to meet your laboratory testing needs, while maintaining the same services, expertise and cGMP compliance available at our facilities.

With more than 2,000 PSS employees serving customers at more than 85 different client sites worldwide, our innovative, award-winning PSS program offers:

- The security of keeping your projects in your facility.
- Insourcing services managed with 60 years of technical expertise.
- A solution to turnover rate and other issues caused by traditional temporary staffing programs.
- Full compliance with co-employment laws and solves the challenges associated with the EU Temporary Agency's Workers Directive 2008/104.
- LEAN Project Support and Management, as well as LEAN Laboratory Design and Validation.
- Cost-savings, and operational excellence metrics to demonstrate the effectiveness and value of the program.
- Flexibility to increase or decrease the size of project teams over time based on long-term project needs.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Project EUUSLA SAT - Department 2009 Routine Testing
Sample(s) / Study(ies) QL19AA9439-1
Lot Number(s) Lot 1
Description SSQL19AA0001-1 Initial
Released On 05-Aug-2019
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Sample / Study Group QL18AA0005
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Project EUUSLA SAT - Department 2004/2010 Water Testing
Sample(s) / Study(ies) QL18AA0005-1
Lot Number(s)
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Released On 25-Jun-2018
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Delivery/Pull Date 16-May-2018
Project EUUSLA SAT - Department 2009 Routine Testing
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Sample / Study Group QL18AA0002
Delivery/Pull Date 24-Apr-2018
Project EUUSLA SAT - Department 2009 Routine Testing
Sample(s) / Study(ies) QL18AA0002-1
Lot Number(s) 13579
Description Suspension Drug Product
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Sample / Study Group QL17AA0036
Delivery/Pull Date 29-Nov-2017
Project EUUSLA SAT - Department 2009 Routine Testing
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Lot Number(s)
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Project Alphora-SAT-Study
Lot Number(s)
Description STUXA19AA0003
Sample/Study Group STUXA19AA0003
Sample/Study Count 1
Delivery/Pull Date 29-Oct-2019
Project Alphora-SAT-Study
Lot Number(s)
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Sample/Study Group STUXA19AA0002
Sample/Study Count 1
Delivery/Pull Date 16-Oct-2019
Project Alphora-SAT-Study
Lot Number(s)
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Sample/Study Group STUXA19AA0002
Sample/Study Count 1
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Lot Number(s)
Description STUXA19AA0002
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Project Alphora-SAT-Study
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Harmonization Drives Quality and Data Integrity

Eurofins BioPharma Product Testing takes rigorous steps to ensure our systems and quality program meet clients' global regulatory requirements. Our network of 39 laboratories worldwide operates under the same strict quality systems and operating procedures, delivering standardization and implementation of best practices globally.

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

These critical systems provide seamless inter-company testing, standardized deliverables and convenient access to data for our clients across the globe. As such, we have a geographically diverse team of 90 IT engineers, testers, and analysts dedicated to building and enhancing our LIMS platform, ELN application and LabAccess Web commerce site.

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 Lab Notebooks

Of paramount importance, our Electronic Lab Notebooks (ELN) system provides a harmonized process for recording and reviewing analytical data. ELN offers an opportunity to maintain compliance, ensure consistency from experiment to experiment, and reduce the time needed for entry, review and approval of experiments.

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

LabAccess.com

A pioneer in providing innovative online data access, Eurofins BioPharma Product Testing's proprietary portal, LabAccess.com[SM] is the most innovative, comprehensive and user-friendly data management tool in the industry. Saving clients valuable time, our secure access platform offers maximum efficiency and 24/7 access to project data, including:

- Listing of current and past projects
- Sample information
- Analysts' notebooks
- Chromatograms
- Lists of tests and test results
- Exporting of results
- Electronic signatures
- Preliminary data reports
- Certificates of Analysis
- PDF images of all raw data
- Quotes, Purchase Orders and Invoices
- Stability Study management tool with links between stability samples and corresponding testing data and results

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