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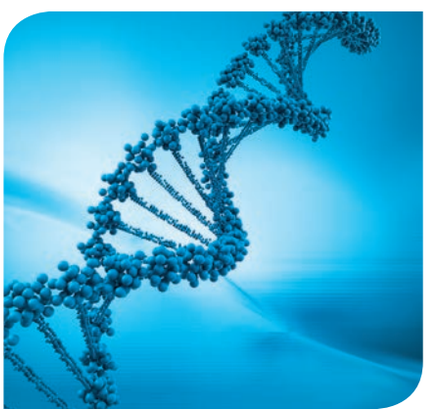
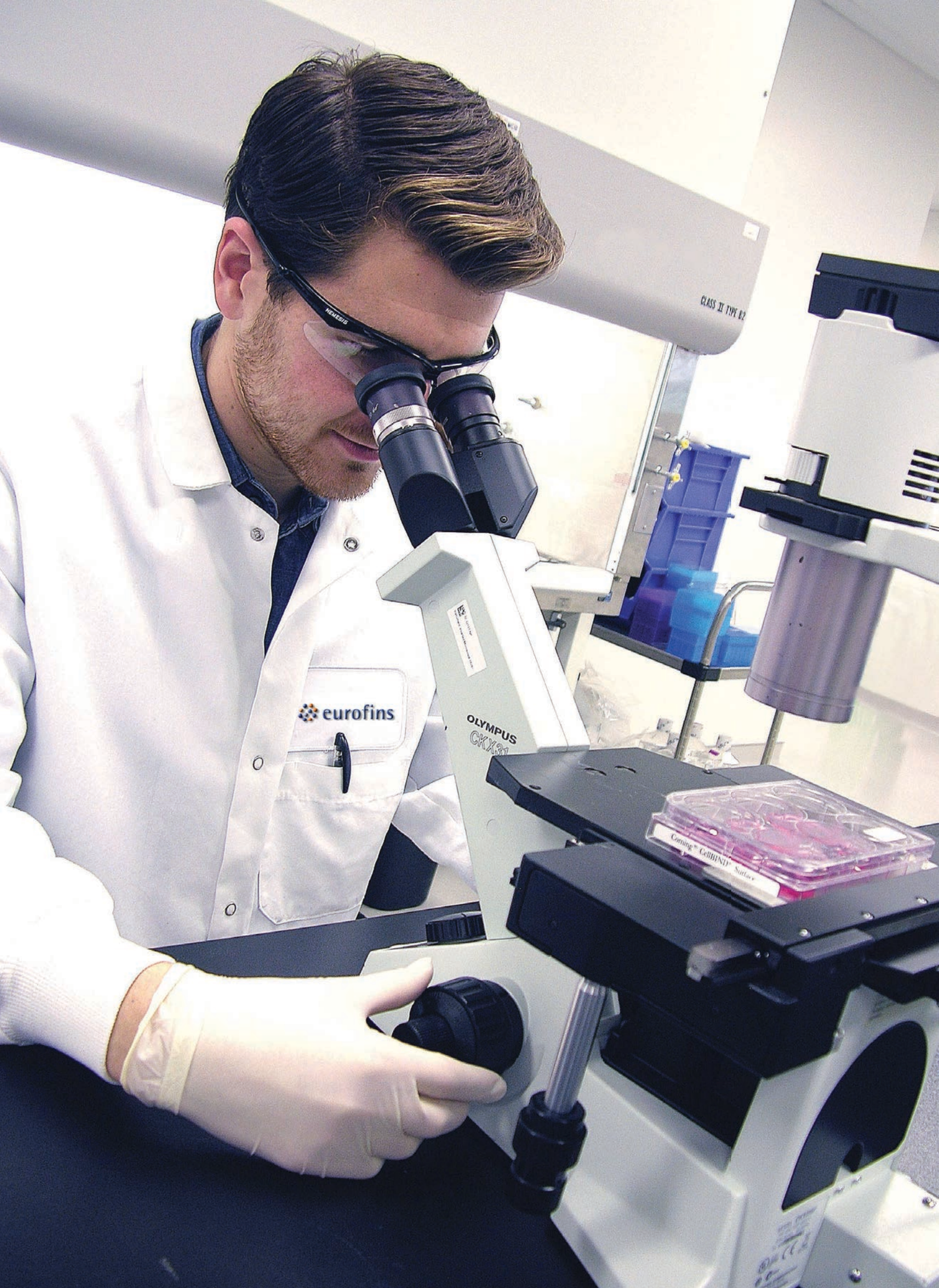
BioPharma Product Testing



The largest network of harmonized bio/ pharmaceutical GMP product testing labs worldwide, Eurofins BioPharma Product Testing enables companies to advance candidates from development through commercialization while ensuring regulatory compliance, cost effectiveness, and achievement of timelines.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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 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
- Extractables & Leachables Testing
- Container & Package Testing
- Residuals & Impurities Testing
- Shipping Studies
- Viral Clearance & Viral Safety Testing
- Bioassay & Potency Testing
- Cell Banking Services
- Stability Testing & Storage
- Raw Materials Testing
- Release Testing
- Critical Reagents/Reference Standards Management
- Disinfectant Efficacy/Cleaning Validation Studies
- Environmental Monitoring
- Facility and Process Validation
- Organism Identification
- Clinical Trial Material Support
- GMP Manufacturing
- Formulation Development
- Professional Scientific Services® (Insourcing Solutions)

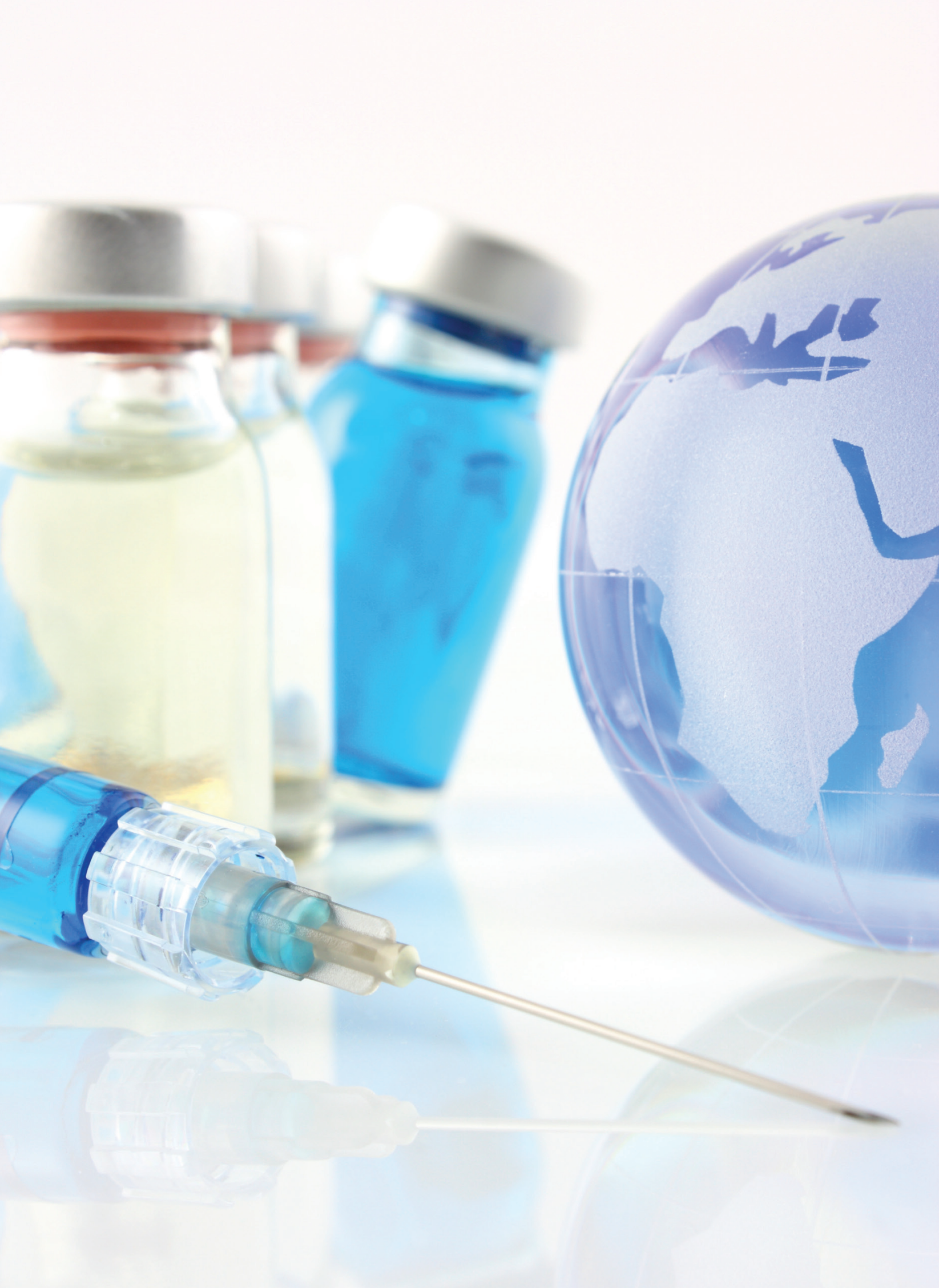
Why Choose Eurofins BioPharma Product Testing?

- As a pioneer in Microbiology, Chemistry, Biochemistry and Biosafety testing for more than 25 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 all analysis are performed according to European and British Pharmacopeia (EP), United States Pharmacopeia (USP) and Japanese Pharmacopeia (JP), as well as specific customer 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.



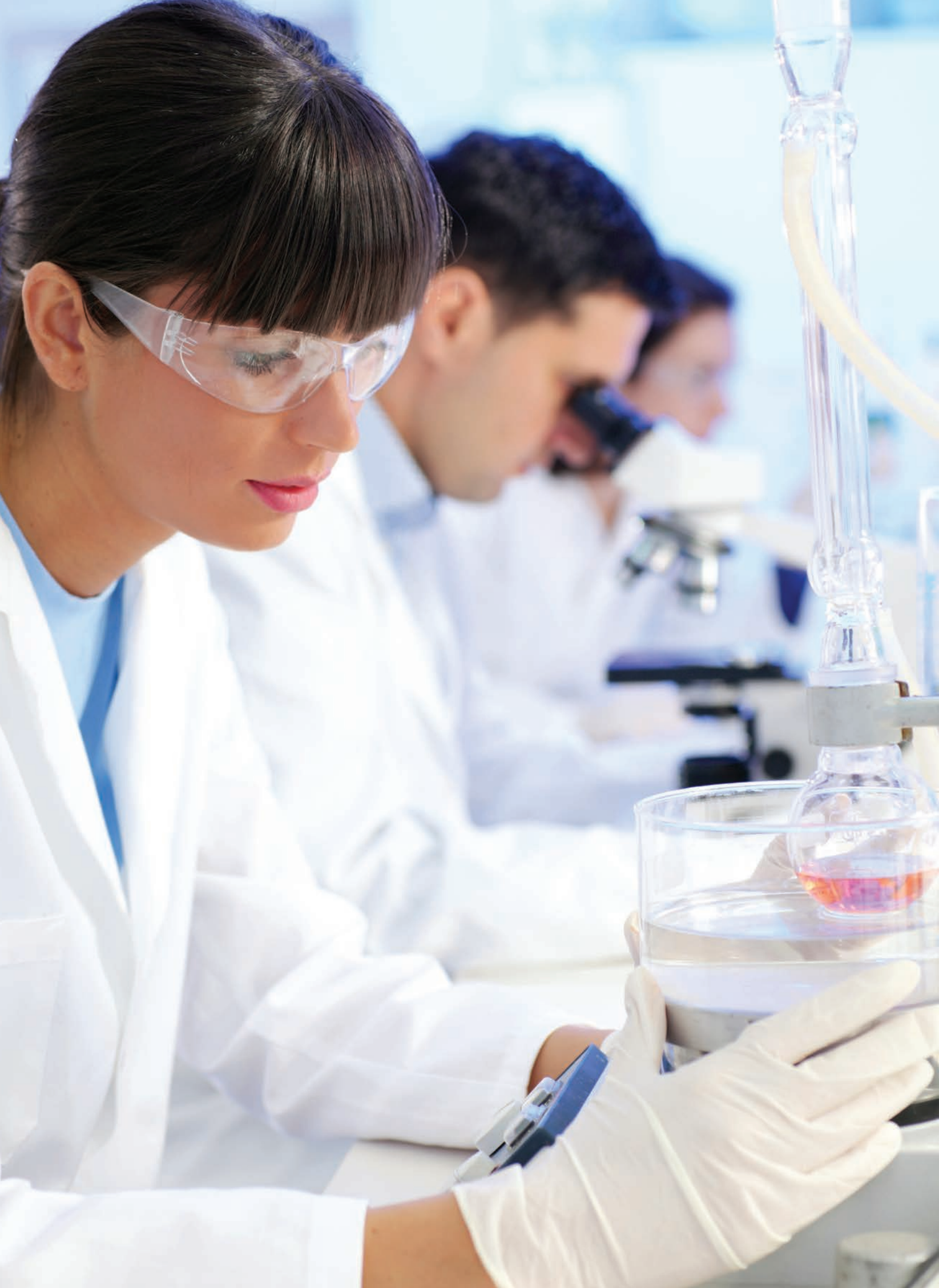
The largest international presence while delivering a true local lab experience

With more than 3,500 employees and a global capacity of 700,000 ft^2 / 65,000 m^2 and 25 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 capabilities (LC/MS/MS, GC/MS, ICP/MS, LC/MS Ion Trap, LC/MS TOF, MALDI-TOF and Orbitrap) and chromatographic capabilities (HPLC, UPLC, CEX, SEC, GC, IC).
- 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 and A/B cell banking suites.
- More than 130 state-of-the-art microbiology laboratory modules, totaling more than 87,000 ft^2 / 8,000 m^2, with multiple sterility suites, including clean rooms and isolator technology.
- More than 200 stability chambers encompassing over 188,000 ft^3 / 5,300 m^3 to accommodate all ICH conditions, including photostability.
- Proprietary organism identification databases, including:
    - Eurofins Microbial Sequencing Index (EMSI) containing over 8,450 validated sequences.
    - Eurofins Microbial MALDI Index (EMMI) containing over 2,200 validated microorganisms.
- Proprietary Extractables & Leachables database, Eurofins Extractables Index (EEI), containing over 1,500 non-volatile compounds.
- GMP NMR Testing services for raw materials and pharmaceutical products, including Pharmacopoeia NMR test methods, as well as custom NMR-based methods and spent media analysis using Spedia-NMR™.
- GMP Manufacturing and support, including:
    - GMP Aseptic Manufacturing (Manual Fill/Finish)
    - GMP Non-Sterile Manufacturing
    - Formulation



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.

Professional Scientific Services® (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 insourced laboratory needs, while maintaining the same services, expertise and cGMP compliance available at our facilities.

With more than 1,400 PSS employees, serving customers at more than 65 different client sites worldwide, our innovative, award-winning PSS program offers:

- The security of keeping your projects in your facility.
- Insourcing services managed with our 55 years of technical expertise.
- A solution to turnover rate and co-employment issues caused by traditional temporary staffing programs.
- Full compliance with co-employment law, as well as the EU Temporary Agency's Workers Directive 2008/104.
- Quality process improvement metrics to demonstrate the effectiveness 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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Online Data Access with LabAccess.com℠

LabAccess.com, our innovative online data access tool, offers you a timely and secure window into comprehensive laboratory information as your project progresses. With LabAccess.com, you can view extensive, live project information such as submitted samples, analyst's notebooks, chromatograms, approved test results, Certificates of Analysis, raw data packages and invoices. Some unique features of LabAccess.com include:

The Stability Calendar

This exclusive feature allows you to view your stability studies in progress. Calendar items have detailed links to information posted; you can link to a sample number and see live data. Additionally, you can link to your overall protocol plan in our document control system, ensuring perfect synchronicity to your requirements and scientific procedures.

Exporting of Results

LabAccess.com enables you to view the results for multiple tests and download them as either a Microsoft Excel Workbook or a Comma Separated Value (CSV) file. You can export your data to perform your own comparisons or to study trends. This enables you to evaluate your product performance over time and compare data sets to statistically evaluate data points.

Raw Data

LabAccess.com can provide access to your raw data, including analyst's notebooks, chromatograms, approved test results, Certificates of Analysis, raw data packages and invoices.

Electronic Signatures

Certificates of Analysis contain our laboratory's QA release electronic signature.

Why Use LabAccess.com?

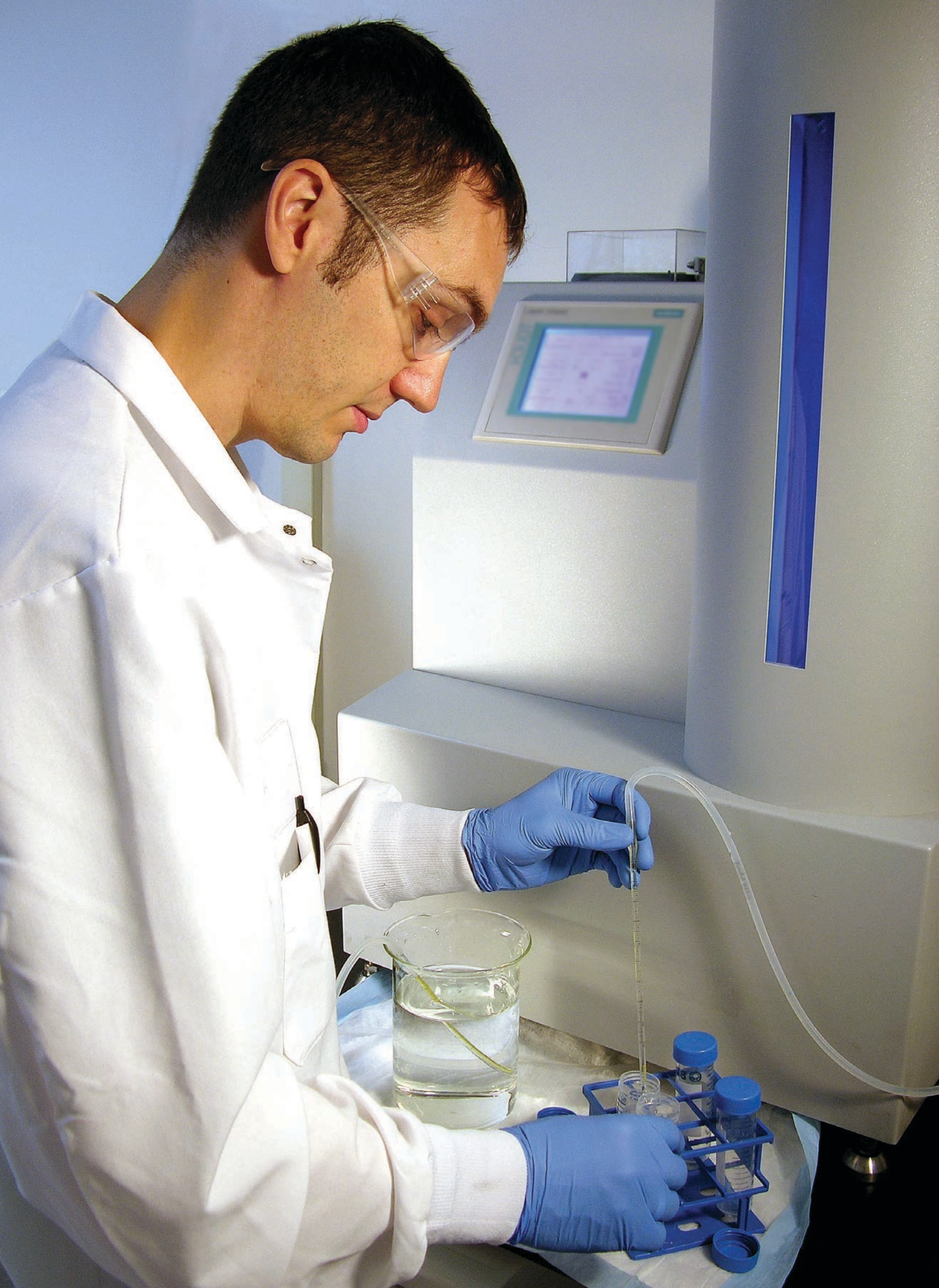
We provide you with the most innovative, comprehensive and user-friendly data management tool in the industry, giving you the ability to save valuable time and manage your projects with maximum efficiency. With more than 6,000 registered users, LabAccess.com offers:

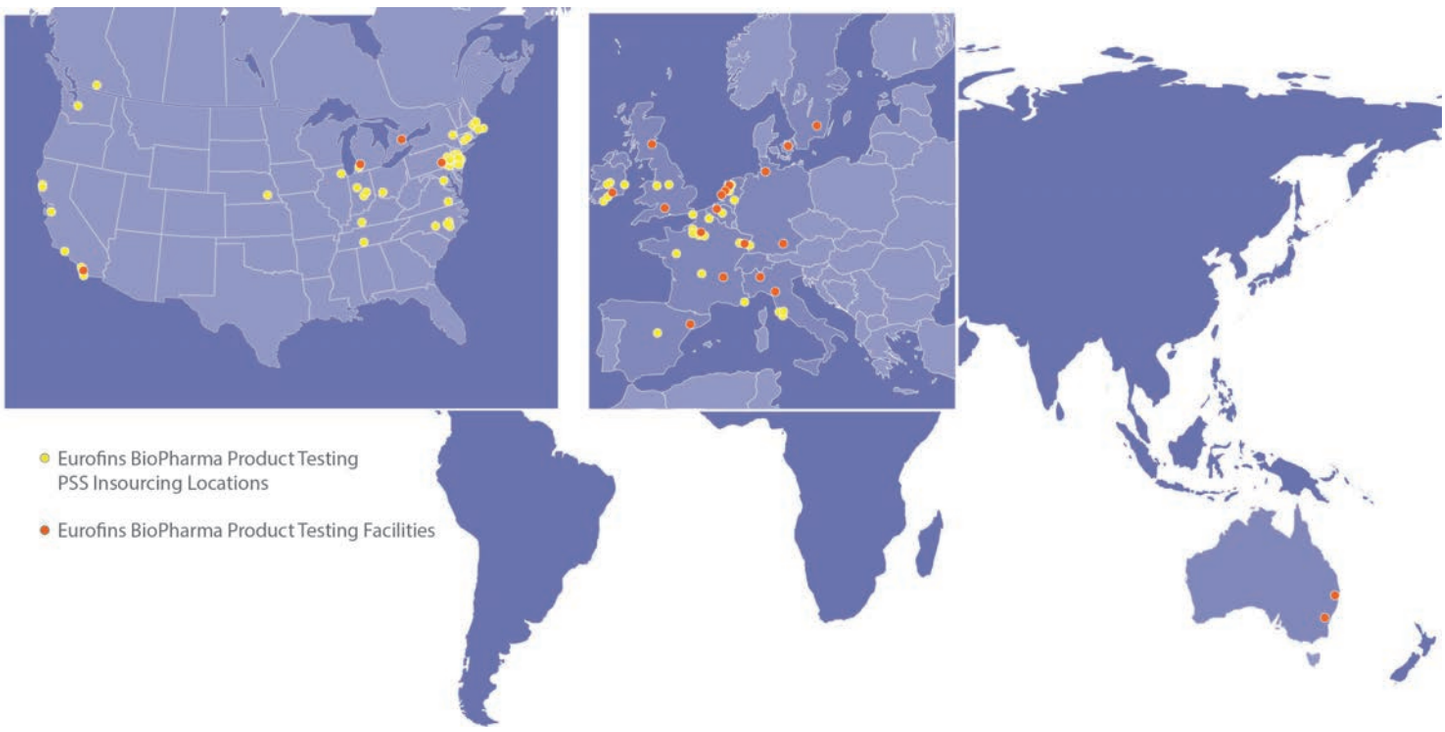
- 24/7 Secure access to your data
- Convenience of retrieving past project information as easily as your current data
- An exclusive Stability Study management tool

What customers are saying about LabAccess.com

"I just wanted to extend my appreciation for the LabAccess.com tool Eurofins Lancaster Labs provides. During the past few days, we urgently needed to access results for old reports and ones that were still pending release on your part. The quickness and user-friendly format of LabAccess.com made this very easy and enjoyable to use. Thank you again for providing such an excellent service!"

- Pharmaceutical Customer





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Eurofins.com/Biopharma | pha@Eurofins.com

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