

BioPharma Services
News
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# Eurofins Central Laboratory supports clinical trials in China's regulatory landscape

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As per guidance from the Chinese National Medical Products Administration (NMPA) regulatory agency, samples taken in the context of a clinical trial are not be exported for laboratory testing abroad. Hence, to support domestic clinical trials in China, or global trials that include Chinese subjects in the study protocol, there is a need for a local central laboratory to assess novel drug compounds for safety and effectiveness. In support of these clinical trials, Eurofins Central Laboratory has been operating a wholly owned and globally harmonised testing facility since April 2008 to allow in-country testing. Local kit packing and distribution for domestic studies were added to the services portfolio in 2019.

In order to meet the increasing complexity of study protocols, the Eurofins Central Laboratory facility relocated to the new Eurofins China headquarters in Shanghai in 2021 to expand its current footprint and facilitate further growth, as well as to accommodate pivotal capacity and capability expansions.

Going beyond standardised safety testing, the Shanghai laboratory is also offering biomarker testing and has recently installed a Meso Scale Discovery (MSD) platform for multiplex biomarker-assays and immunoassays. The site is fully harmonised, so as to partake in the Eurofins PBMC network for effective harvesting, processing, cryopreservation, and shipping for storage or downstream analysis of peripheral blood mononuclear cells (PBMCs). Globally harmonised Flow Cytometry capabilities are available in all four Eurofins Central Laboratory facilities in China, the US, the Netherlands and Singapore. Furthermore, DNA extraction and Real Time PCR will be added to the portfolio of capabilities soon. This expansion of Central's laboratory testing service offering will allow solution-based services and improve efficiencies in the drug development life cycle in compliance with the Chinese regulatory landscape.

For more information, visit *www.eurofinscentrallaboratory.com*

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# Eurofins BPT Italy develops Container Closure Integrity Testing for Biologic Drugs with Pressure Decay technique

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Assuring the sterility of a parenteral drug product, prior to any human use, is a mandatory regulatory requirement. Sterile products should not contain contaminants caused by microorganisms, gases or debris, and the chosen Container Closure System (CCS) has to prevent the ingress of such substances throughout the entire shelf life. The ability of the CCS to maintain the integrity of its physical barrier, and hence the sterility of a drug product, has to be demonstrated through Container Closure Integrity Tests (CCIT).

Biologic Drugs (BDs) are products that are manufactured from living organisms or contain their components. Due to the nature of these products, they often contain large molecule ingredients such as proteins, other biologics polymers, and sometimes entire cells. The main challenge of the CCIT on this type of drug product is ensuring that these ingredients do not affect the defect detection capability of the method. For example, during the testing of liquid-filled packaging with the Vacuum Decay technique, the test vacuum conditions may trigger some substances to solidify inside leak paths, causing a false negative result.

A common CCI technique applied to the BDs is the High Voltage Leak Detection, but this has some limitations related to the physical state of the product, as it can only be used for liquid products, and to the type of packaging tested.

The R&D work at Eurofins BioPharma Product Testing Italy led to the development of the Pressure Decay technique as a valid approach for testing the integrity of CCS used as primary packaging for different protein-based BDs.

This analytical technique proved to be effective at overcoming some critical issues that usually occur during the CCI method validation, demonstrating the following advantages:

- Leak detection both in the headspace and below fill level.
- Suitable for test products with different physical states (e.g. powders or liquid products).
- Not affected by the presence of moisture on the package.
- Exploitable in leak detection in packages with different materials, including leaks into the material-change region (e.g. glass vials stoppered with a metal crimp cap).
- Non-destructive testing.

For more information, visit: *www.eurofins.com/media/ebr/article/pressuredecay/ebptitaly2022.pdf*

# Eurofins PSS Insourcing Solutions® celebrates 20 years of bringing managed laboratory services to clients' sites and exponential global growth

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20 years ago, Eurofins PSS began as a big experiment. A Virginia (VA), USA, client was experiencing a challenge: they needed to keep some testing in-house yet struggled with co-employment and performance challenges regarding temporary staff. They requested that the Eurofins laboratory in Lancaster, PA, reverse their service model and offer testing services at their VA site rather than outsource samples. So with innovation and passion to meet client needs, PSS was founded to recruit, hire, train and manage highly qualified scientists to perform laboratory testing services at the client's site. And ever since, great chemistry was made.

Transforming clients' science into an outstanding service experience, Eurofins PSS has grown exponentially since its inception 20 years ago, offering the most client-awarded managed laboratory testing services in several industries, including Biopharma services from early phase development to GMP finished product testing, consumer product testing, food, and environment testing. Today, PSS still serves that first client along with 85 other client sites, offering services in 16 countries across North America, Europe, and Southeast Asia through its talented team of 3,000 employees.

One of Eurofins PSS secrets to success is the simple premise of forging long-lasting relationships: take great care of employees, and they'll take great care of clients. Building in operational excellence in combination with creating a culture of positivity and engagement through employee empowerment and recognition enables Eurofins PSS to attract, retain and motivate high-caliber employees to better serve clients at their sites. Turns out, it's good for people, and good for business.

Join Eurofins PSS in celebrating this milestone as we continue to build on our successes and wonderful relationships and further enhance our great places to work, drive innovation, and deliver superlative service for both employees and clients. For more information, visit: *www.eurofins.com/pss-insourcing-solutions/*

# Eurofins BioPharma Product Testing Europe earns ISO 14001 certification – The global Environmental Management Standard


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We all have a duty to play our part in efforts to protect the natural world and achieve sustainable climate objectives. In line with this perspective, Eurofins BioPharma Product Testing Europe has decided to promote and implement the International Standard ISO 14001 by introducing an Environmental Management System. Through earning the certification, sites were challenged to improve their environmental performance through more efficient use of resources and reducing waste.

The certification process began early in 2021 and involved 12 countries, encompassing 32 Eurofins BioPharma Product Testing Europe sites, with full dedication from both site managers and laboratory staff. Adherence to the ISO 14001 certification shows that the organisation has a Management System that keeps the environmental impacts of its activities under control and systematically seeks improvement in a coherent, effective and, above all, sustainable way. Thanks to the commitment and contributions of everyone involved, certification was achieved as early as March 2022. Eurofins' network of European BioPharma Product Testing laboratories demonstrated the will of the organisation to enhance environmental performance by mitigating and preventing adverse environmental impacts to help protect the planet. Through innovation, hard work and passion, the teams achieved ISO 14001 environmental objectives by controlling and influencing the way our organisation's services are designed, manufactured, distributed, consumed and disposed of. For more information about how your company can minimise its negative impact on the environment, visit: *www.//cdnmedia.eurofins.com/corporate-eurofins/media/12158026/eurofins/esgreport2021/final.pdf*

# Eurofins BPT Kyoto offers foreign matter analysis services for CGT products

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Like many consumers, Japanese society is typically very concerned by the contamination of products with foreign matters. For example, if a consumer found a foreign matter in their food, it would not be uncommon for this to immediately be taken up by the media and have a major impact on the manufacturer of the food. When it comes to pharmaceuticals, the impact can be even more severe, with some companies suspending the manufacturing of pharmaceuticals until the source of contamination has been formally identified, once a foreign matter has been found. It is therefore not only accuracy that is critical for foreign matter analysis, but also speed. Eurofins Analytical Science Laboratories, Inc. (E-ASL) has more than two decades of testing experience and has continually met the needs of clients by utilising a variety of analytical techniques customised for the type, size, and condition of foreign matters.

Recently, with a shift of modalities, pharmaceuticals such as cell and gene therapy (CGT) products, which require biosafety control, have also appeared, and in turn, the necessity of foreign matter analysis for CGT products has also increased. To respond to several requirements brought about by this shift, E-ASL launched a new service in 2021 and set new rules for the handling of samples up to BSL1 in a new 300m$^2$ laboratory. Since then, E-ASL has consistently received more than 25 requests each month. Due to the special techniques required for sampling foreign matters, E-ASL offers these services limited to BSL-1 at this time, but preparations to expand to BSL-2 by devising the necessary techniques is in progress.

BPT Kyoto was a company within the Astellas Pharma group before joining the Eurofins Group in 2018. Many of its analysts have expertise in the manufacturing processes of pharmaceuticals. This experience makes it possible to not only provide reliable results but also to infer the cause. By providing foreign matter analysis services for CGT products over time, it will be possible to continue building trusting relationships with clients. For more information, visit: *www.eurofins.co.jp/eurofins-biopharma-product-testing-kyoto/*


# Eurofins Viracor expands and moves to a new, 110,000 ft$^2$ purpose-built facility in Lenexa, KS

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Eurofins Viracor is excited to share that it recently completed the construction of a new state-of-the-art facility and has officially relocated to a beautiful new home in Lenexa, Kansas. The new structure will house Eurofins Viracor company headquarters, along with all laboratory testing equipment and personnel.

The relocation and expansion, in response to continual growth in client demand, are consistent with its organisational goal of providing more comprehensive solutions for clients. Building on a new site afforded the company the opportunity to create a purpose-built facility where it can maximise flexibility and efficiency of operations. Moreover, as current and future testing demand has continued to grow, Eurofins Viracor was on track to exceed the capacity of the current location within the next few years. The new, 110,000 ft$^2$ facility nearly doubles the previous footprint, enabling Viracor to address increasing demand for molecular and immuno-assay development and testing services to support growth in vaccine and precision oncology development.

The move itself was a resounding success, without disrupting any services during the relocation. Similarly, Viracor has also avoided any significant delays to ongoing client projects or studies as a result of the move. This success is attributed to a combination of the tenacious project leadership of the former President, Scott Mattivi, the many duplicate systems that were temporarily established at both sites to help ensure a smooth transition, and the heroic efforts of a great many dedicated associates and partners.

The company will occupy all of the new facility, which allows for expanded molecular/genomic, next generation sequencing, immunoassay, cell-based, LCMS, and other bioanalytical testing services. This is in addition to increased processing automation and ultralow biostorage capabilities to ensure Viracor is positioned to meet the changing needs of clients well into the future.

Triggered by continued growth and client-focused strategic expansion, Eurofins Viracor has created a space that encourages collaboration to help facilitate the development of life-advancing therapies across the globe. The team looks forward to continuing to provide quality results and excellent service from the new facility.

The address of the new facility is:
Eurofins Viracor BioPharma Services
18000 West 99th Street
Lenexa, KS 66219

For more information, visit: *www.eurofins-viracor.com/biopharma/*