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BioPharma Services News

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Eurofins' Analytical Support Helps Biopharma Organizations Navigate Clinical Trials

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Regulatory agencies throughout the world have the responsibility of protecting public health by assuring the safety and efficacy of bio/pharmaceutical products and medical devices. Clinical trials are a critical and essential activity of the drug development process for gaining "medical knowledge" of these products. Therefore, it is incumbent upon biopharmaceutical organisations to sponsor clinical trials in order to demonstrate safety and efficacy to the regulators. Clinical trials require a tremendous amount of analytical testing, which is often outsourced to Contract Research Organisations (CROs). Eurofins BioPharma Services supports biopharmaceutical clients with a wide array of testing services that cover many aspects of clinical trials.

Eurofins Central Laboratory provides information on the response of patients enrolled in clinical trials through the testing of blood, urine, etc. The Central Lab offers the synergy of integrated safety assessment, biomarkers, therapeutic drug monitoring, genomic testing, and microbiology. This Lab performs a comprehensive menu of routine and customised safety and efficacy tests, including biochemistry, hematology, urinalysis, flow cytometry and many more to support clinical research programmes of any size and complexity.

Eurofins BioPharma Product Testing focuses on another aspect: the biopharmaceutical products themselves used in the clinical trials. Well characterised, representative products must be available for the trials. The BioPharma Product Testing laboratories offer a wide array of testing services to support sponsors throughout the clinical trial process. This lab transfers or develops and validates analytical methods to ensure the potency, purity and stability of clinical materials, including the drug products and raw materials used to manufacture them. Further, some study protocols require that tablets and capsules are overencapsulated in order to "blind" them to the patient and sometimes the physician (double blinded). Eurofins BioPharma Product Testing provides extensive testing that must be done in order to show the product release profile is consistent with the "virgin" product. This is a common approach in comparator product testing. Before clinical trial materials are administered to patients, the team performs extensive stability and release testing under cGMP.

In this issue, you can read many other examples about how Eurofins BioPharma Services supports global clients' clinical diagnostic testing needs, including news from Eurofins Genomics, Boston Heart, Viracor-IBT, Eurofins Bioanalytical Services and Eurofins Lancaster Laboratories Professional Scientific Services. For more information on global testing services, visit: *www.pharma.eurofins.com.*

Boston Heart transforms the treatment of cardiovascular disease

Cherie Lucier, Senior Director, Corporate Identity and Communications, clucier@bostonheartdx.com

Through the acquisition of Boston Heart, Eurofins strengthens its clinical testing and genomic service offering with a strong entry in the specialised cardiology diagnostic segment. In combination with the acquisition of Viracor-IBT in 2014, this acquisiton gives Eurofins an excellent position in two important segments of the specialty diagnostic testing market, thereby significantly enhancing its overall capabilities focusing on preventing life-threatening diseases. Boston Heart also expands Eurofins' genomics capabilities with a promising selection of patient-focused tests and proprietary tests to clients in the pharmaceutical industry.

Cardiovascular disease (CVD) remains the number one cause of death in the U.S. Of those who die of heart attacks, 50 percent have normal LDL cholesterol. Nutrition and lifestyle management is the first line of defence in CVD, but it is not actively pursued by millions of patients. In addition, compliance with prescribed medication continues to be a major problem.

Since 2007, Boston Heart has been transforming the treatment of CVD by arming healthcare providers with diagnostic insights that give a more detailed view and new perspective on treatment plans. The Boston Heart exclusive programme measures a patient's HDL particle concentration, identifies the source of cholesterol production, provides guidance on the best treatment options and engages patients in a novel way.

The insights from Boston Heart's CLIA-certified advanced CVD laboratory tests allow individualised treatment reducing or even eliminating the "trial and error" medicine that many patients suffer through and a major reason for non-adherence to treatment plans. Boston Heart helps providers identify patients at true underlying risk of CVD by going beyond the "good" and "bad" cholesterol assessment to give a more complete and individualised picture of heart health. Boston Heart has a rich history in evidence-based medicine and research that supports its highly focused test menu not offered by any other laboratory.

Patient reports help explain test results and treatment considerations in language and imagery that every patient can understand. All of the content in the reports is personalised to the individual patient providing their unique heart health story based on lab results from lipid, inflammation, metabolic and/or genetic tests. Boston Heart's fully integrated and scientifically designed nutrition and lifestyle management programme is supported by its team of registered dietitians accessible to patients by phone. This integrated programme has the power to engage patients differently and change the way providers and patients communicate about disease.

Boston Heart is providing an innovative and fresh approach to CVD patient management by using high value diagnostics to allow treatment and power personalised communication tools designed to improve health literacy, patient engagement and adherence to treatment plans. The result is better patient outcomes.

For more information, visit: *www.bostonheartdiagnostics.com*.

Ultrasensitive GLP-compliant Singulex® Erenna® Immunoassay Services

By Craig Draper, PhD, Commercial & Marketing Manager, Eurofins Bioanalytical Services, CraigDraper@eurofins.com

Protein biomarkers provide insights into the safety, efficacy and target population during drug development. The successful implementation of a biomarker strategy provides both time and cost savings, resulting in better medicines available in the clinic faster. Typically, protein biomarkers are detected in blood or other bodily fluids using a combination of techniques and technologies called Ligand Binding Assays (LBA).

Current generation LBAs routinely detect proteins down to the 1-10 pg / mL range. For years, this level of sensitivity has limited the biomarkers that can be used during drug development to those that had a concentration above this technological sensitivity barrier. This inability to routinely and robustly measure biomarker levels below the pg / mL range results in valuable protein biomarker signatures going undetected and unused.

Recently introduced advanced instrumentation has improved the sensitivity of protein biomarker assays, enabling the detection of protein biomarkers well below the pg / mL levels. The Singulex® Erenna® platform uses a digital ELISA approach that is able to detect proteins as low as the femtogram / mL levels, a 1000 fold improvement in sensitivity over existing approaches. The system uses a well-established assay reagent format coupled with the Erenna instrument that employs single photon digital capture of the assay signal to achieve the ultra-sensitive levels of detection. In addition to performing assay services using commercially available kits for key biomarkers, Eurofins Bioanalytical Services develops and validates custom immunoassays on the Erenna platform, extending the application of the system beyond biomarkers to use in pharmacokinetic studies and also in the evaluation of the immune response to large molecule therapeutics, especially where detection levels are a challenge. The system can be used for exploratory studies or methods can be validated for GLP compliance.

For more information on large molecule bioanalysis, biomarkers and biosimilars, *visit www.eurofins.com/bioanalyticalservices*.

Viracor-IBT Laboratories delivers results faster, when it matters most

Jenni Miller, Viracor-IBT Laboratories Marketing Manager, jenni.miller@viracoribt.com

A Medical Director of a hospital Bone Marrow Transplant programme recently told a Viracor-IBT Laboratories associate, "Every day Viracor-IBT helps me save lives and helps improve my patient care. We used to send Cytomegalovirus (CMV) [testing] to another lab. It took a few days to get a result. We switched to Viracor-IBT because they offered one day turnaround time, which is what I needed for my very sick patients. Since I switched to sending to Viracor-IBT, I have not seen a single case of CMV pneumonitis. It's been years. We have eliminated it. I would say that is lifesaving."

With over 30 years of specialised expertise in infectious disease, immunology and allergy testing for immunocompromised and critical patients, Viracor-IBT is committed to high quality service, helping medical professionals, transplant teams, reference labs and biopharmaceutical companies get results faster, when it matters most. Eurofins acquired Viracor-IBT—one of the largest privately-held, esoteric reference laboratories servicing the specialty diagnostic market—in mid-2014. With industry-leading turnaround times as short as eight to 10 hours from sample receipt to result reporting, Viracor-IBT is focused on helping physicians treat time-sensitive patients. Additionally, pharma companies, biotechs, CROs and central labs rely on Viracor-IBT to transfer, validate and optimise assays addressing study-specific needs for Phase I through Phase IV clinical trials. Viracor-IBT is based in Lee's Summit, Missouri, with a satellite lab in Los Angeles, California. Its testing capabilities include quantitative and qualitative PCR, DNA sequencing, ELISA and other immunoassay platforms.

The 280+ associates at Viracor-IBT are passionate about delivering value to their clients, never losing sight of the connection between the testing performed and the patients served. This acquisition further demonstrates Eurofins' commitment to serve the emerging needs of the clinicians, pharmaceutical and biotechnology leaders with laboratory services of the highest quality and reliability.

For more information, *visit: www.viracoribt.com*.

GMP Oligonucleotides for IVD and ASR Applications

Custom cGMP services with highly standardised process controls to support pharmaceutical drug development process as it advances through clinical trials and on to commercial production.

Carola Grimminger, Marketing Manager Eurofins Genomics, carolagrimminger@eurofins.com

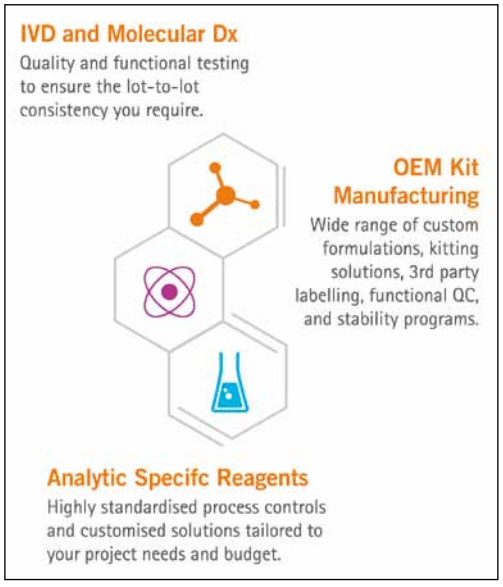
Regulatory requirements must adhere to highly standardised process controls along the product development cycle. They are applied during discovery, development and through the commercialisation of products and services.

Especially the GMP (Good Manufacturing Practice) standard is required to be adapted in pharmaceutical manufacturing. It is the highest quality standard that can be achieved for the production and testing under this level of manufacturing.

During the past years since the FDA approved the first oligonucleotide-based therapeutic, compounds based on synthetic oligos have established themselves as critically important tools for life scientists. A growing number of companies are developing oligonucleotide-based pharmaceutical products, which are in various stages of pre-clinical testing. As a result of this increasing activity, the requirement for GMP manufactured synthetic oligonucleotides for pre-clinical testing and eventual in vivo use becomes increasingly important. The DNA and RNA oligonucleotide synthesis has gained industry importance with proven therapeutic and molecular diagnostic (Dx) applications. To meet the growing demand of cGMP manufacturing for IVD (in vitro diagnostic) and ASR (analytic specific reagents) for laboratory developed tests (LDTs) within the pharmaceutical market, Eurofins Genomics offers a new oligonucleotide process control.

As a global leader in a wide range of genomics products and services, Eurofins Genomics introduced cGMP products to support clients' needs - from pilot projects through to the manufacturing of small and large scale cGMP oligonucleotides, which require regulatory documentation.

The company is internationally recognised by the ISO 9001, ISO 13485 certification and FDA cGMP registration for use in IVD products. Through continuous risk management processes, comprehensive batch records, traceability and dedicated account contact persons, clients have streamlined access to products with highly standardised process controls, documentation and a map of expected milestones.



Eurofins Genomics is flexible and committed to provide cost-efficient client solutions for their pharmaceutical drug development programme. For more information, visit: *www.eurofinsgenomics.eu/*.

PSS enhances name to better reflect insourcing services; named separate legal entity

Lisa Bamford, Eurofins Lancaster Laboratories Communications Manager, LisaBamford@eurofinsUS.com

Over the past 13 years, Eurofins Lancaster Laboratories Professional Scientific Staffing (PSS) has grown dramatically to employ more than 1,000 global staff, serving clients at more than 40 locations in over 10 countries. To clearly delineate and reflect the broad scope of services to clients, the legal name has been changed to Eurofins Lancaster Laboratories Professional Scientific Services, LLC, replacing Staffing with Services to accurately reflect insourcing services.

As PSS has grown its insourcing solutions to meet client's evolving needs, this name enhancement reflects an expansion from offering staffing services in 2002, to delivering comprehensive laboratory management insourcing solutions today. And the new PSS logo--Eurofins BioPharma Product Testing PSS Insourcing Solutions--reflects this growth and evolution of services and capabilities in the US and Europe.

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From a business standpoint, it remains business as usual. Capitalising on more than 50 years of Eurofins Lancaster Laboratories quality testing success, PSS will continue to bring this expertise to clients' sites and provide outstanding insourcing solutions, delivering cost effective and strategic partnerships to clients. In addition to the award-winning PSS service model, Eurofins Lancaster Laboratories also offers the traditional Fee for Service and Full Time Equivalent service options, helping clients balance market demands and fixed drug development cost challenges and effectively allocate their research and manufacturing expenditures through variable cost solutions.

Timothy S. Oostdyk, Ph.D., President, Eurofins Lancaster Laboratories, and Sr. Vice President, Eurofins BioPharma Product Testing Group has named Beth DiPaolo,M.A., President of the new PSS legal entity, Eurofins Lancaster Laboratories Professional Scientific Services, a wholly-owned subsidiary of Eurofins Lancaster Laboratories, Inc. "Beth has led the PSS business since its inception, and she and her team have done an outstanding job of serving Eurofins' customers and strategically developing insourcing solutions," says Dr. Oostdyk. "Our objective going forward is to ensure that clients receive the strategic partnership and full value of all of the service models and services available globally from Eurofins Lancaster Laboratories and Eurofins BioPharma Product Testing group."

For more information on this award-winning insourcing solution, visit *www.eurofins.com/biopharma*.

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