Bio/Pharmaceutical NEWS

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Delivering a true local lab experience with the largest global network of harmonized GMP BioPharma Product Testing sites

Timothy S. Oostdyk, Ph.D., President, Eurofins Lancaster Laboratories, Sr. Vice President, Eurofins BioPharma Product Testing Group

As the largest global network of harmonized BioPharma GMP product testing laboratories, our fundamental philosophy is to enable clients to effectively allocate their research and manufacturing expenditures by strategically engaging them to meet their unique outsourcing needs.

Listening to our clients' exciting new product development goals, global regulatory approval requirements and budgetary and timeline challenges, inspires and ignites a drive to be there for them--literally--wherever they are in the world.

Developing and releasing products in many different markets, our clients require the same consistent level of expertise, quality, best practices, and service options to be delivered across our network.

And that is why, as our business has grown around the world, to effectively serve clients' needs, our BioPharma Product Testing Group offers harmonization among our 14 GMP facilities, located in nine countries. The same quality system. The same LabAccess customer interface. The same individualized customer service. All right in our clients' backyard.

The result of our harmonization initiatives is that all of our laboratories operate under the same Global Quality Policy Manual and utilize the same CAPA/Exceptions Management System and Document Management System. This ensures efficiency for our customer's audits, and consistency in the approach, content and quality of laboratory investigations.

Further, with our global online portal, LabAccess.com, clients working with any of our laboratories are able to review project data and reports 24/7. Project information such as reports, test results, and status of samples for any project within the Eurofins BioPharma Product Testing network are available through this secure online portal.

By working with one harmonized international biopharma GMP product testing provider, Eurofins' clients can appreciate various enhanced capabilities and benefits. Among all of our labs, we require collaboration on services, regulations and new technology and ensure that our laboratories operate with a concordant level of scientific expertise. This drives consistency and excellence for clients marketing products in various regulatory environments. (See opposite page for examples of collaborative initiatives for clients grappling with multiple regulatory authority approvals.)

Our harmonized network supports all functional areas of bio/pharmaceutical manufacturing, including method development, microbiology, process validation and quality control. Further, our network provides testing for nearly all stages of the drug development process, ranging from pre-clinical through post-product approval, including: testing of all starting materials, process and product related impurities, method development and validation, stability and release testing, process/facility validation, virus clearance and safety, and testing of packaging components.

Beyond the breadth of our service offerings, as many of our clients know and appreciate, our value is really enhanced by our service models. Specifically, in addition to our Fee-For-Service capabilities, we have also harmonized all service models to include our Managed Hours program, Full Time Equivalent program, and our award-winning Professional Scientific Staffing^{SM} program, which has grown to include more than 35 locations in seven countries.

We believe strongly that this harmonization and collaboration among our global Eurofins BioPharma Product Testing sites greatly enhances our ability to serve our customers. While providing a true local lab experience, our international presence ensures the most complete range of global testing services, where you need them.

We make it our business to effectively balance delivering the most complete range of GMP harmonized testing services on a global platform, while meticulously treating each client as if they were our only one.

On behalf of our nearly 2,000 employees, thank you for your business and for the trust you have placed in us. We look forward to continuing to serve you.

Contact us

For information on services, literature requests or address changes, please contact: Bio/Pharmaceutical Business Development, 717-656-2300 or pha@lancasterlabs.com

See how our Flexible Service Models can meet your project needs at: LancasterLabsPharm.com.

GMP BioPharma Product Testing laboratory network provides both US & EU product release support to global organizations

Jon S. Kauffman, Ph.D., Senior Director, BioPharmaceutical Sciences

Biopharmaceutical sponsors typically market products in multiple regions under different regulatory authorities, and therefore must identify, qualify and contract with both US and European laboratories. Eurofins Biopharma Product Testing Laboratories' expertise in bringing products to the market under both the US and EU regulatory environments allows our global clients to work with just one organization, utilizing our harmonized quality and IT/LIMS systems.

For example our Lancaster, US, site validated a variety of methods to support a client's NDA submission and their release testing in the US. This client then needed to find a European laboratory to support them with their Marketing Authorization Application (MAA) filing in the EU within a short timeframe. Our Milan, Italy, laboratory quickly evaluated the methods and determined that they were capable of running them. The analytical method transfer (AMT) protocol development was a collaborative effort among our client, the Lancaster lab, and the Milan lab. A method verification approach was taken and described in the protocol, including the analytical testing to be performed and the acceptance criteria to be met for system suitability, specificity, accuracy and precision. All methods were transferred successfully, and the Milan lab was qualified to perform testing to meet the client's timelines and EU requirements.

In another example, we had been supporting a critical release testing program in the US for a product in short supply, when the client approached us with the request to support the EU release testing also. A risk-based analysis of the methods was performed. The more critical, higher-risk methods were transferred through parallel testing, in which samples were run at both sites with the Lancaster, US, site as the reference laboratory and its Ireland site as the receiving laboratory. Subject matter experts (SMEs) from Lancaster traveled to the Ireland site to perform hands-on training of the technique-sensitive methods. The transfer protocol described the number of replicates (typically n = 6), as well as, the acceptance criteria for percent relative standard deviation (%RSD) and absolute differences between labs. Again, all methods were successfully transferred and our client can release product in both the US and EU.

Finally, we are taking another approach for method implementation for some of our large biologics programs. One of our clients required labs qualified in both the US and EU to support their monoclonal antibody stability and release programs. Therefore, the method implementation at two sites was accomplished through method co-validation. The protocol described the testing of critical validation parameters such as intermediate precision and accuracy to be performed at both sites (and at our Munich, Germany, facility in the case of cell-based assays). This allowed for simultaneous method implementation.

Critical success factors of these method installation projects include strong project management, effective communication, extensive coordination among the US and EU laboratories and the client, collaborative protocol development, and SME driven training. This all results in shorter timelines and reduced costs to our global clients.

Eurofins BioPharma Product Testing scientists in Lancaster (left) and Milan (right) collaborate with a US-based client on an analytical method transfer to support their Marketing Authorization Application filing in the EU.

Cell Banking Capacity, Suites and Storage Expand

Jeri Ann Boose, PhD, Senior Director, BioPharmaceutical Sciences

This summer and fall, Eurofins Lancaster Laboratories (ELLI) will expand its current cell banking capabilities by doubling the number of cell banking clean-room suites from two to four, by adding long-term cell banking storage for both production and non-production cell banks, by increasing the maximum bank size from 400 to >1000 vials, and by offering insect cell bank production and testing services.

For many years, the Cell Banking Group at Eurofins Lancaster Laboratories has prepared a wide

variety of mammalian cell banks in support of GMP production, GMP non-production (e.g., banks for bioassay) and in support of R&D needs. Currently, the two suites used for the preparation of GMP production banks are designed to meet ISO5/ISO7 FDA clean-room requirements. Specifically, in these suites, the cell banks are prepared in an ISO5 biosafety cabinet within an ISO7 environment. The two new suites that will open this summer will meet the more stringent EU requirements of having a Grade A critical area within a Grade B environment. The new suites will therefore enable our global clients to prepare their production master and working cell banks in an environment that without question will be acceptable to EU Regulatory Authorities. All GMP-production cell banks are manufactured as campaign banks unless otherwise requested by the client. In addition, the equipment needed to support the preparation of insect cell banks will be available in our new suites, and concurrently, the assays to support insect cell bank characterization will also become available later this year.

ELLI also provides extensive support to clients who are in need of non-production master and working cell banks. These non-production banks are typically used in cell based potency assays that are part of the lot release testing panel for a given product. In response to the increasingly frequent requests for large banks of ready-to-use cells to support these assays, ELLI is currently validating the fill of banks exceeding 1,000 vials at the cell concentration specified by the client. This service will be offered concurrently with the opening of our new clean-room suites this summer.

Finally, ELLI will now offer long-term storage solutions to our cell banking clients. Clients may now elect to store part or all of their banks at our facility in Lancaster, PA. This service will be offered in the fall of 2014.

The combination of these expansions to our facilities and service offerings, along with our high level of technical expertise in cell banking and characterization, and our extensive project management tools have been designed to provide you with a single-source solution for all of your cell-line needs. Please contact your Project Manager or Business Development Representative for more information.

THE CRO LEADERSHIP AWARDS 2014 Quality Award

Eurofins Lancaster Laboratories has earned the 2014 CRO Leadership Award. This is the second consecutive year the company has been awarded this top industry honor.

The CRO Leadership Awards recognize companies achieving top 20 percentile perception scores in key areas. *Life Science Leader*'s annual CRO Leadership Awards are determined by industry-leading market research conducted by Nice Insight. More than 40,000 pharmaceutical and biopharmaceutical executives responsible for making or influencing their company's outsourcing decisions are invited to participate in Nice Insight's annual survey. This year's survey received over 10,000 responses, according to the publication.

Eurofins Lancaster Laboratories was recognized as a winner in the following four categories for 2014:

Quality – Business treats the project as if it were their own

Reliability – Business meets all project milestones and timelines

Productivity - Business delivers on agreed objectives

Innovation - Business enhances in-house capabilities through new ideas, methods or devices

Operations Spotlight: On the Raw Materials Department

Travis Emig, Senior Director, Pharmaceutical Chemistry

The Eurofins Lancaster Laboratories Raw Materials Department in Lancaster, PA, has experienced tremendous growth. At present, the team is comprised of nearly 80 scientists. Full analytical coverage includes two shifts plus a dozen operation leaders.

This department supports a wide variety of activities, including full compendia testing for USP, EP and JP requirements, water chemistry, API and reference standard qualification, trace metals and residual solvent determinations. Newer services offered include XRPD identification and trace metals testing conducted in a controlled clean room environment.

Reasons for demand increases include several common themes found in the pharmaceutical industry today. Headcount restrictions, changes in published compendia, QC units required to qualify their ability to successfully execute test methods in their respective laboratory environments, and CMO operations that do not possess full technology capabilities are many of the drivers leading to increased outsourcing decisions.

Our team has focused on establishing an efficient organizational structure, including numerous process controls that allow for high quality testing to be performed with maximum productivity and attention to delivery deadlines. In 2012, the department was divided into two unique groups: one supporting the assessment, installation and qualification of all analytical procedures not previously run at our facility; the other focused on release testing using established methods with a single objective to meet delivery commitments. In 2013, we aligned a dedicated team of data review specialists focusing entirely on this department.

So what's our strategy to sustain further growth in this area?

The continued addition of staff and expansion of our current laboratory footprint is ongoing. Eurofins Lancaster Laboratories is projecting to staff nearly 100 individuals in this department by the end of 2014.

A dedicated sample receipt team with extensive compendia based experience has been established to support quick and accurate entry of samples and analyses into our LIMS system. This group will quickly resolve any discrepancies with information from customers prior to analytical work commencing.

We will work diligently with customers in strategic ways. We have identified quick wins with such initiatives as requesting potential lists of materials that may be coming to our facility from a customer, and we in turn pre-stock items such as compendia standards (especially EP and JP specific materials) so delays from supply chain roadblocks and customs are mitigated. Specific technical management oversight of fully outsourced customer programs and having communication channels for knowing when shipments are processed have allowed pre-staging activities for samples en route to our facility. Our staff understands manufacturing operations today are often "Just in Time" processes, timelines are short, emergencies occur, and we rally our staff to meet those demands. We attempt to arrange discussions with new customers prior to samples being submitted to our facility as an on-boarding effort, establishing clear understanding of our processes and full disclosure of how we operate as well as what to expect from us.

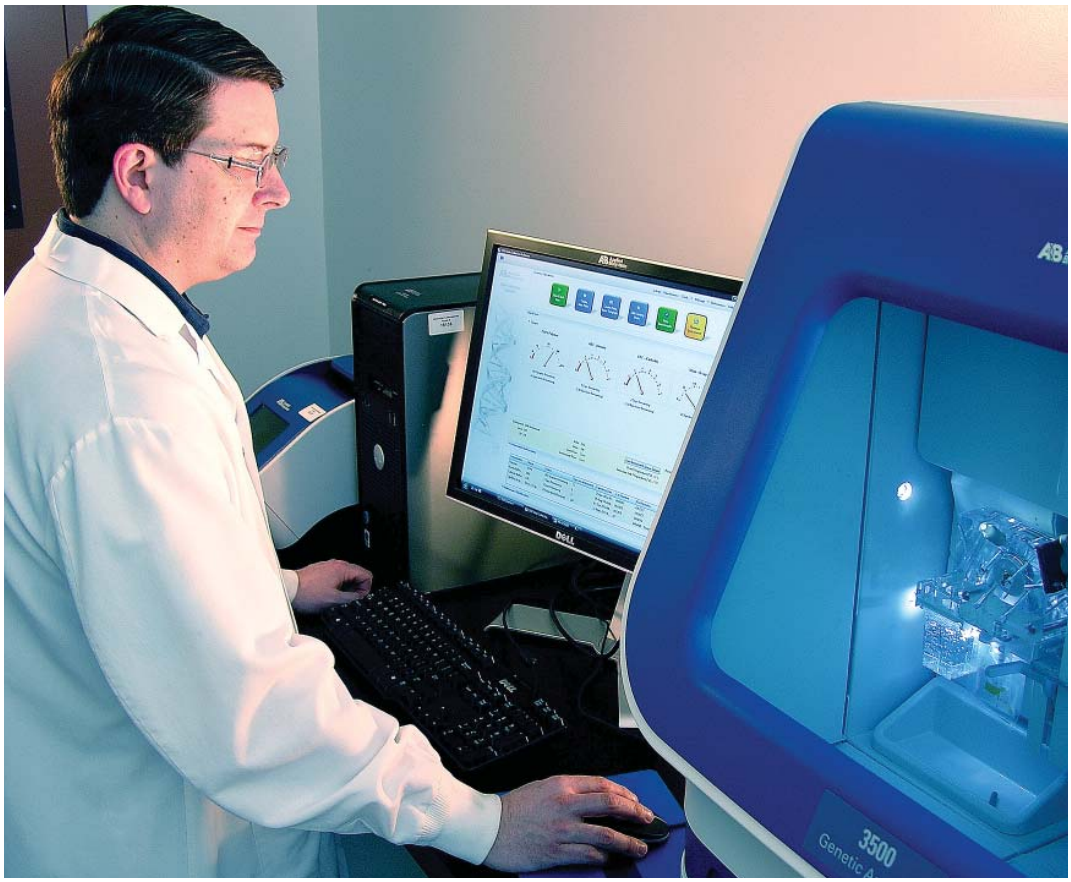
Moving forward, Electronic Notebooks (ELN) will pave the way to immediate review and release of data once testing is complete. Significant efforts are being made to roll out ELN processes into this operation in 2014.

Our objectives are to provide released reports for testing that has been established at our site in eight business days (shorter than industry standards of 10 business days). We are striving to provide manufacturing support and accept realistic rush requests as frequently as needed. We specialize in method establishment, method development and consulting on the performance and reliability of compendia methods. We will continue to engage our customers and strive to become an extension of their organization.

For more information, contact Pharmaceutical Business Development.

Eurofins BioPharma Product Testing boldly goes beyond ID capabilities with IDmyk acquisition

Mark Kaiser, Senior Director, Microbiology, Stability Services and Lancaster Laboratories Midwest



Eurofins Biopharma Product Testing Group has expanded and enhanced its identification capabilities with the acquisition of IDmyk, a laboratory specialized in identification and molecular typing of microorganisms.

IDmyk, located in Lyon, France, offers the largest proprietary databases for sequence-based identification of bacteria, yeast and molds. The databases contain over 8,450 type strains of organisms relevant to the GMP regulated bio/pharmaceutical industry and are updated regularly with new organisms through a validated process. The use of double stranded long sequencing (1,350 base pairs) for bacteria as a standard approach improves the accuracy of the identification when compared with the partial sequencing (500 base pairs) commonly used in the bio/pharmaceutical industry. Multilocus Sequence Analysis (MLSA) is available and uses simultaneous comparative sequencing of multiple housekeeping genes of taxonomic interest and extended databases of reference sequences to increase resolution and further discriminate organisms at the species level.

IDmyk also offers extensive molecular typing services to generate fingerprints of isolates to determine if they correspond to different strains of the same species to support manufacturing contamination investigations. Services include MultiLocus Sequence Typing (MLST), Arbitrary Primed PCR (APPCR), Variable Number of Tandem Repeats (VNTR), Pulse Field Gel Electrophoresis (CHEF) and MicroSatellite Analysis (MSAT).

Integration of the IDmyk databases for sequence analysis into the Eurofins Biopharma Product Testing network of laboratories, including the microbiology laboratory in Lancaster, is in process and will provide a single global platform for clients using multiple Eurofins locations.

In addition, Eurofins Lancaster Laboratories (ELLI) has added the capability to identify bacteria using MALDI-TOF to its suite of identification services. MALDI-TOF provides a phenotypic identification using the unique protein patterns generated by organisms. ELLI uses the Bruker Biotyper platform and its validated database of over 4,600 organisms. ELLI is also expanding the reference library on an ongoing basis with the addition of species relevant to bio/pharmaceutical manufacturing environments and products. All entries to the library are confirmed through a formal validation process. The MALDI-TOF service option can provide clients with cost-effective identification in very short timeframes, including same-day service, and is ideal for routine identification of isolates from environmental and utility monitoring programs.

The addition of MALDI-TOF, the largest libraries of reference bacteria and fungi available worldwide for sequence analysis and specialized molecular typing through IDmyk, provides our clients with comprehensive identification services and the option to choose the appropriate level of identification to fit their needs, be it the identification of an environmental isolate or the analysis of an isolate from a critical investigation such as a media fill or sterility test failure.

For more information on identification capabilities, including sample submission instructions, pricing and turn around time, please contact BioPharmaceutical Business Development at 717-656-2300.

People are the chemistry

At Eurofins Lancaster Laboratories, we believe that our people provide our strength. Their dedication to quality, professional competence and hard work are the key elements in the company's success. In this regular feature, we introduce you to some of the people who have helped make Eurofins Lancaster Laboratories an industry leader.

Chris Gilmer brings more than a decade of experience to his new role as Group Leader of Organism Identification. He recently earned certification in the American Society for Microbiology's National Registry of Certified Microbiologists (NRCM). The goals of the NRCM are to: minimize risk to the public by identifying qualified microbiologists, encourage mastery of microbiological knowledge and skills that contribute to improving the human condition and foster professional pride and a sense of accomplishment in qualified microbiologists. Successful candidates must meet stringent education, work experience, and proficiency exam criteria. Read more on what Chris brings to the bench:

What does your current job entail?

I have recently assumed the Group Leader position of the Organism Identification Group within the Bio/Pharmaceutical Microbiology Department. As we provide internal support testing for the department and offer direct service to client submissions, the daily coordination of operations seem endless. I perform daily review of the current workload for priority scheduling, release of completed testing to internal or external clients and constant evaluation of a wide variety of incoming projects. Involvement in lab operations allows for the most accurate and timely status information, so I enjoy contributing to sample processing, data interpretation and technical troubleshooting. In support of our entire laboratory operation, I serve as the equipment administrator for our environmentally controlled chambers. This demands 24/7 availability to ensure continuous operation under specified conditions. Drawing on previous experience within our Non-Sterile Products Testing Group, I periodically contribute to various bioburden, microbial limits and preservative testing projects.

What is the scope of your group?

The Organism Identification Group utilizes a variety of testing solutions to deliver our clients reliable results. We support our internal testing groups with identification of any microbial isolates recovered, as well as provide identification results for our internal environmental monitoring programs. Clients utilize our direct submission service for environmental monitoring and for manufacturing confirmations or investigations. We perform a variety of tests from morphological to gene sequence characterization.

Why should clients trust us with their projects?

Our group has always been staffed by a dedicated team of analysts with very specialized experience. We have been restructuring our service model to provide our clients with cost-effective solutions to meet their needs and expectations. Sample processing efficiencies have been improved while incorporating timely notifications to clients with status updates. The company has recently invested in emerging specialized identification services to place us in a highly competitive position within the industry.

How would you characterize your leadership style?

Having recently assumed the Group Leader role with a close continued focus on lab operations, I remain aware of the daily challenges at the bench level. The improved efficiencies implemented in the group are proving most effective with a complete team presence in the lab for prompt decision-making, communication, and troubleshooting. I continue to identify opportunities to lead by example and influence a continuous focus on service quality and client satisfaction.

And when you're not working?

Outside of work, I enjoy camping trips and hiking with my wife Jen and our high-energy boxer Jake. When the weather is nice I try to make time for bike rides. Over the past few years I've gained an increasing interest in cycling for exercise and as a way to get out and see more of Lancaster County.

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Can We Talk?

PDA/FDA Virus and TSE Safety Conference:
Kate Bergmann, PhD, will present a poster on *Inactivation of Viruses by UVC Treatment,* June 9-10, 2014**.**

View Our Webinar Series

- **Navigating the Analytical Development Challenges for Bioprocess Residuals and Impurities**
- **Alternative Rapid Mycoplasma Testing Methods for Biopharma Products**
- **UV-C Treatment—a New Procedure for Viral Inactivation**
- **Chemistry and Microbiology Perspectives on Cleaning Validations and Disinfectant Efficacy Studies**
- **Best Practices for Extractables and Leachables Testing**
- **Effective Strategies for Managing Comparator Product Testing**
- **Outsourcing Cell Based Potency Assays: Perspectives from a Sponsor and a Contract Testing Laboratory**
- **Critical Aspects of Antibody-Drug Conjugates: Structural Characterization and Analysis**

For registration information for future webinars and access to past webinars, visit LancasterLabsPharm.com.

Look for us at...

PDA/FDA Virus & TSE Safety	June 9-11	Bethesda, MD
Viral Safety for Biologics	June 24-25	Germany
PR Chemist Convention	July 28-Aug 3	Carolina, PR
Analytical Land O' Lakes	Aug 4-7	Madison, WI
Symposium on the Practical Application of Mass Spectrometry	Sept 9-12	Napa, CA
Contract Pharma	Sept 18	New Brunswick, NJ
BioProcess International	Oct 20-23	Boston, MA
PDA Annual Global Conference on Pharmaceutical Microbiology	Oct 20-22	Bethesda, MD
Well Characterized Biologicals	Nov 3-4	Washington, DC
AAPS Annual Meeting	Nov 2-6	San Diego, CA

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