

BioPharmaceutical NEWS Spring 2026



From continual advancements in automation and IT, vast expertise in regulatory compliance, achievements in sustainability, to building and geographic footprint expansions, Eurofins BioPharma ProductTesting has manifested a magnificent growth trajectory for the past 65 years.

Read more in this Issue

Advancement and approach in automation 2

Beyond the bench: the true operational cost of running a QC lab 3

USP <665>: risk assessment can be a powerful tool 4

Safeguard patient safety by understanding needle-based combination product design verification and validation 5

Growing sustainably for 65 years 6

People are the chemistry 7

Eurofins Medical Device Services welcomes EAG St. Louis Chemistry and Medical Device Testing teams 8



eurofins

**BioPharma
Product Testing**

Pictured above is the Lancaster, PA, 21st and largest building addition at 300,000 ft² to be completed in 2027.

Advancement and approach in automation



Daryl Krushinsky, Senior Director of Operations, Eurofins BioPharma Product Testing

These days, it is nearly impossible to go more than a few hours without hearing about new uses and advances in automation. These breakthroughs continue to pick up speed at a rate that can be hard to keep up with. Automation is nothing new within the Biopharma industry as automated manufacturing lines, high-speed instrumentation, and large capacity autosamplers (for example) have been in place for decades.

However, implementation on a large, “transformative” scale within most Biopharma laboratories is relatively early phase. As we fully automate transport of materials, laboratory preparations, and ultimately perform analytical testing with reduced analyst interaction, we will define and reshape the future of the industry.

This potential is exciting, but it can create a bit of uncertainty and skepticism as navigating GxP regulations and requirements can be quite challenging. Additionally, within Eurofins BioPharma Product Testing, there is added complexity that arises from the very nature of our business as a contract testing laboratory. Unlike a manufacturing facility with a standardized product line (high throughput, low mix), we perform unique and customized testing for hundreds of clients (high throughput, high mix) on a daily basis. To ensure our automation dreams become a reality and our AMRs (autonomous mobile robots) move full speed ahead, we complete extensive workflow evaluation and planning.

Like many companies, we started the au-

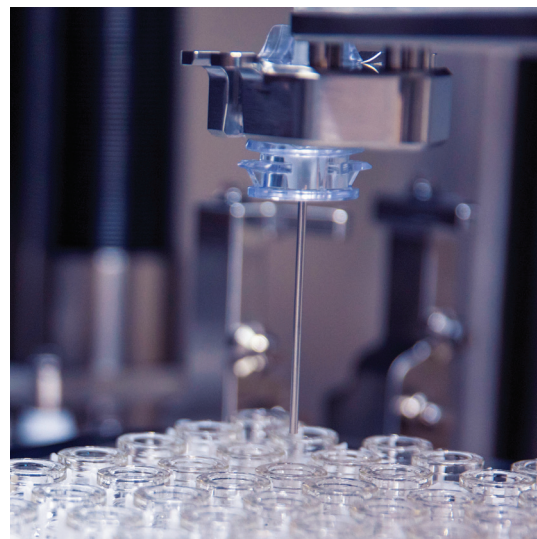
tomation journey by implementing several off-the shelf commercial solutions. Since custom programming isn’t required, and configurable inputs adjust to meet various method requirements, these systems offer relatively quick implementation. Automated pipetting devices and labelers improve sample preparation speed and quality by reducing errors. They also improve safety by reducing analyst repetitive motion strain. Additionally, introducing high-speed analytical instrumentation with software that automates sample result analysis is another early phase step in the automation journey. Unfortunately, implementing multiple stand-alone systems results in multiple stops and gaps in the overall sample testing workflow. The next logical step is to create a seamless end-end workflow.

We utilize many in-house developed platform methods, and we support client developed methods. Differences in laboratory preparation steps between methods is extreme. Sample mixing alone can be accomplished via sonication, vortexing, inverting, or swirling to name a few. Standardizing client preparation methods is not possible, making it a challenge to develop an automated solution that can handle every variation. Instead, we are developing and planning to incorporate custom automation to provide transport on the bench between existing commercial solutions and instruments. This requires interface with various automated pipettors, mixers, and labelers mentioned previously. There must also be an interface developed for various analytical instruments.

Transport of materials on the bench, within the laboratory and/or between laboratories and buildings, is a significant and visible milestone that will truly transform laboratory operations. It is somewhat commonplace for cobots (collaborative robots) and humans to work side-side in manufacturing settings. However, having a robot deliver various testing materials to a work station, prepare testing components, and/or interface directly with an analyst or analytical instrument in a contract laboratory is a new frontier. While these transport interfaces are available commercially, they are often vendor/model/material specific. In the contract laboratory business, a single vendor/model/material solution won’t service all clients. Balancing the implementation of custom solutions and

commercial solutions requires more space. To this end, we are actively designing and building new facilities and renovating laboratory space at multiple sites to accommodate automation efforts that are already being planned and researched. Current initiatives include automated sample intake processing lines to streamline workflow, transport AMRs for efficient material movement, and benchtop labware and solution preparation stations to enhance accuracy and throughput.

In addition to physical building upgrades and robotic enhancements, digitalization plays a crucial role in driving automation. Replacement of analog with digital devices and integration of instrumentation with internal software platforms such as ELN and LIMS contributes to real-time data ingestion/analytics, informed decisions, and improved GxP ALCOA data integrity principles. Digitalization supports and enhances automated operations beyond what physical and robotic improvements alone can achieve.



Considering the scope of analytical services that we provide and the initiatives noted above, it is evident that careful planning must occur to accomplish this. In addition to evaluating each new automated process and workflow, we must also evaluate and ensure that various implementation steps do not impact current capacity or quality compliance. We are committed to implementing automation solutions that will improve safety, quality, and efficiency. Appropriate planning and design of systems will promote growth and value for our employees AND clients. To find out more about how we can support your automation strategies, contact your Eurofins representative or: [Contact-Us](#) to submit an inquiry.

Beyond the bench: the true operational cost of running a QC lab

Matthew Rodak, Scientific Director, BioPharma Chemistry Raw Materials; Andrew Schaefer, Scientific Director, Analytical Method Development & Validation

You sit down to start a seemingly normal day managing your QC lab. A day full of juggling manufacturing timelines, ongoing investigations, problematic method troubleshooting, etc. Then you open the dreaded email from a vendor. The message states the software the lab is using will no longer be supported by your operating system; the hardware will be discontinued by the end of the year; and they are releasing a brand-new software platform. This one message introduced potential IT vulnerability and compliance risk.

You immediately become flush with stress putting together a mental checklist of the impact to your operation. Do I have the IT infrastructure to support the changes? What is the impact to my vali-

but with every aspect of the supply chain to manage a QC laboratory operation. And it's not the only recurring cost of running your QC.

QC laboratory operations are a significant, ongoing cost whether run internally or outsourced. How do I even start to determine if I should start up my own QC operations, outsource to a contract testing organization (CTO), or a combination of both? Then exactly what services do I need to support? How many global markets am I operating in? How often do materials need testing, and are my vendors qualified?

The task is daunting and often leads to overlooking recurring costs. The fundamental question any lab manager needs to ask for return on investment of building a lab operation: what is my break-even point? Can a break-even be achieved in a high cost, high investment QC operation?

Annual Tests	Internal Lab Costs Compared to Eurofins
40K	1.4X
20K	1.5X
10K	1.6X
Start Up	28X

for compliance, QA, and overall time required to gain expertise in compliance. The cost of removing resources from core competencies such as product R&D and commercial manufacturing must also be considered. Beyond labor, to start up a lab, cost of building and/or retrofitting facility space must be included.

Taking all these factors, potential break-even points were calculated between outsourcing vs internal resourcing at different volume levels, highlighted above. This exercise demonstrates that break-even is not achieved at the highest test volume levels in support of commercial manufacturing.

How does Eurofins BioPharma Product Testing achieve a structurally lower-cost model? The biggest factor is economies of scale. Eurofins BPT performs hundreds of identification and quality tests and numerous other compendial and platform methods each month for dozens of customers, maximizing instrument utilization and distributing maintenance, calibration, and method update costs across a broad testing base. This stands in stark contrast to internal laboratories, which often experience instrument idling, under-utilized staff, and high-fixed operating costs.

Eurofins' instrumentation breadth is another core advantage: maintaining the full suite of equipment required to support large scale QC testing is prohibitively expensive for most organizations. Beyond cost, Eurofins demonstrates regulatory maturity through proactive compendial surveillance, participation in standard setting organizations, and mature lifecycle management practices. These capabilities ensure continuity, method compliance, regulatory readiness, and rapid adaptation to evolving standards. Finally, Eurofins' position as an industry leader allows for future investment in laboratory operations, such as automation and robotics (p. 2). For more information visit: www.Eurofins.com/BPT or: [Contact-Us](#) to submit an inquiry.




Let's look at an example of ongoing cost structures of a raw materials QC laboratory. Why look at raw materials as a case study? Every phase of every operation needs the testing, and raw materials testing is historically a large overhead operation, although, not significantly different than many other QC operations.

Graphic at left depicts the main categories of ongoing costs a fully compliant QC lab will incur. These are ongoing costs NOT including labor costs. Labor cost is not just a line item—it is a sustained management effort that includes hiring, scheduling, training, and turnover coverage.

dated methods? How many SOPs need updating or creating? How do I train the staff on the updates, etc? The cherry on top: I didn't budget for any of this!!

While this seems extreme, this is happening more and more often and not just with software and instrumentation,

These hidden demands can materially shift breakeven assumptions and delay realization of internal-lab ROI. An accurate cost model must also include time and costs such as quality engineering (metrology), system administrators, staff for monitoring compendia changes



USP <665>: risk assessment can be a powerful tool

Patty High, Manager, Extractables & Leachables Testing; Kate Knapp, PhD, Group Leader II; Extractables & Leachables Testing, Eurofins BioPharma Product Testing

USP <665> became official on May 1, 2026, bringing updated expectations for extractables testing grounded in scientific rationale and risk-based decision making. While the chapter introduces new requirements—including qualified analytical methods—it can be implemented smoothly with thoughtful planning. The revised framework provides clearer, risk-aligned guidance that supports reliable extractables testing without unnecessary burden.

Earlier drafts lacked clarity or imposed prescriptive requirements, but the final USP <665> reflects a more balanced, practical approach. It emphasizes scientific justification, well-designed studies, and testing strategies aligned with patient risk—aimed at generating meaningful, defensible data rather than testing for its own sake.

Eurofins' Extractables and Leachables (E&L) teams have reviewed the updated chapter, developed a strategic implementation plan, and created templated protocols aligned with its key elements to meet client challenges.

Risk assessment as the foundation

A robust, well documented risk assessment is central to any USP <665> strategy. It justifies testing decisions, aligns programs with regulatory expectations, and clarifies what requires testing—and what does not.

When applied effectively, risk assessments can reduce the number of components tested, shorten timelines, and eliminate low value work. Although this requires upfront effort, it often leads to meaningful time and cost savings. Eurofins' E&L teams leverage extensive

experience to deliver defensible risk evaluations paired with fit-for-purpose study designs.

How risk drives testing under USP <665>

The official chapter introduces clearer expectations and stronger scrutiny, with testing decisions explicitly tied to risk. As USP <665> becomes enforceable, documentation quality and scientific justification grow increasingly important.

Materials are categorized as low, medium, or high risk, with testing requirements scaled accordingly—from basic screening techniques (UV/Vis, NVR) to full orthogonal chromatographic and spectrometric analyses. This tiered approach strengthens scientific rigor while avoiding unnecessary testing.

Expanded scope beyond final packaging

USP <665> broadens extractables assessments beyond container-closure systems. Manufacturing components that contact materials are now included, reflecting their potential contribution to patient exposure. This expanded scope supports more realistic risk evaluations and reduces regulatory gaps.

Evolving expectations around AETs

Analytical Evaluation Thresholds (AETs) remain a challenge, especially for large volume or high dose products. Under USP <665>, extractables must be evaluated against a calculated AET based on clinical use and patient exposure. This may result in lower thresholds and more reportable compounds requiring toxicological assessment.

Alternative thresholds must be scientifically justified and thoroughly documented, underscoring the need for early planning and cross functional alignment.

Manufacturing strategy matters

Successful implementation depends heavily on manufacturing strategy. Inhouse vs CMO manufacturing affects data availability, traceability, and risk assessment quality. CMOs may not always provide USP <665> ready data packages, and gaps in material information must be addressed early to avoid delays. Strong communication with manufacturing partners is essential.

Planning early for success

Effective USP <665> programs begin with early information gathering—confirming material status, understanding manufacturing strategy, and determining whether risk assessments will be conducted internally or outsourced. Internal assessments may reduce cost but require expertise; outsourced assessments are often faster and more defensible but depend on data quality. The right approach depends on internal capabilities and timelines.

Key takeaway

USP <665> is now a reality, and preparation is essential. With strategic planning, risk assessment becomes a powerful tool rather than a regulatory hurdle. Early alignment reduces cost, delays, and rework; while a strong scientific framework keeps implementation manageable.

Eurofins partners with clients to navigate this evolving landscape, applying USP <665> in a practical, fit-for-purpose manner that focuses resources where they add the most value while maintaining strong regulatory defensibility.

Eurofins BPT takes pride in being a trusted extension of your organization. For more information visit: www.Eurofins.com/BPT or: [Contact-Us](#) to submit an inquiry.

Safeguard patient safety by understanding needle-based combination product design verification and validation

Tyler Harris, Senior Scientific Advisor; Ryan Bair, Manager of Medical Device Package Testing/CCIT; Medical Device Services, Christina Mendat, Vice President Eurofins Human Factors MD

Bio/pharmaceuticals have rapidly shifted from conventional small molecule products to complex biologic modalities, often delivered by injection. Historically, administration occurred in medical facilities by healthcare professionals. Over the past decade, new product configurations have accelerated growth and shifted point-of-care administration to the home through combination products.

Combination products may be device-led, or more commonly, drug-led. Device constituents include auto-injectors, prefilled pens, and on-body delivery devices (OBDD), with automated or semi-automated features that require in-depth design verification and usability testing.

Design verification

For drug-led combination products, design verification demonstrates the system meets mechanical, functional, stability, and user requirements so both drug and device constituents perform under expected use conditions. Design Verification Testing Protocols vary by intended use, critical quality attributes (CQAs), critical material attributes (CMAs), usability, regulatory expectations, and risk.

Requirements and compliance

Combination products are regulated by the agency overseeing the primary mode of action. For drug-led devices, CDER provides final product approval, while the device constituent must still comply with applicable CDRH requirements.

Risk (ICH Q9 and ISO 14971) and Quality by Design (ICH Q8) underpin design and design verification by encouraging

a holistic view of the device and drug constituents across the product lifecycle.

Component level

Each configuration needs a tailored set of component-level assessments (e.g., primary and secondary containers) to confirm functionality and build a foundation that reduces primary-container risk. Standards and guidance, including ISO 11040-4/-6/-8, ISO 80369-20, ISO 11608-3, and USP <382> address elastomer performance, physio-chemical interactions between drug and package, container closure integrity, and standardized dimensions. Testing includes:

- Break-loose force
- Extrusion force
- Closure system liquid leakage
- Tip-cap pull off force
- Inherent integrity
- Needle self-sealing capacity

Assembled level

Assembling the primary container into the device constituent warrants additional assessment of the resulting combination product. Complex mechanical systems can fail due to manufacturing issues (e.g., injection molding processes), fitment problems, and assembly variability. Guidance and standards for assembled needle-based injection systems (e.g., ISO 11608-1, ISO 11608-5, FDA Guidance for Industry) emphasize mechanical, automated, and usability specifications and provide data to support design verification.



Usability and human factors

Component performance can look acceptable in bench testing yet create real-world challenges for intended users that reduce usability and market viability. For example, excessive break-loose or cap-removal force may cause sudden release and physiologic hand rebound, increasing the risk of inadvertent needle exposure, accidental activation, or loss of control. If the force needed to overcome break-loose is too high, users may experience strain or injury, incomplete dose preparation, or unintentional medication loss.

At the assembled level, user-based testing should include early-stage, formative, and late-stage (end-stage) evaluations, since user performance can only be validated on the final finished product.

Conclusion

Safeguarding patient safety starts in the design phase and continues through the product lifecycle. Testing and inspection support this goal by helping deliver quality, user-friendly needle-based injection systems. Eurofins supports manufacturers by expanding our auto-injector testing footprint and onboarding universal test systems that can sequentially measure cap removal, activation force, deliverable volume, click detection, injection time, needle depth, and needle lock-out. This approach can reduce sample quantity needs, lead times, and cost.

For more information, contact us at: Medical-Device@BPT.EurofinsUS.com

Growing sustainably for 65 years



Christina Leslie, Vice President, Corporate Sustainability & Operational Efficiency, Eurofins BioPharma Product Testing, North America

In 2025, the Eurofins BioPharma Product Testing North America business line began construction of three new facilities for our Cary, NC; San Diego, CA; and Toronto, Canada, operations. These state-of-the-art facilities will come online in 2026. Additionally, our Lancaster, PA, site commenced construction for its 21st and largest – 300,000 ft² – building expansion in Q2 2026. And with every expansion and laboratory renovation, our business strategy for managing sustainable growth is carefully considered and approached in a variety of ways.

We build sustainability into expansion plans at the onset of the project, not after. This has been accomplished by taking into consideration energy efficiency, water conservation, and green campus infrastructure opportunities. For example, we integrate LED lighting in newly constructed buildings, implement on-going conversion efforts to replace older lighting technology with LED lighting in existing facilities, and use low-flow and reuse water systems in restrooms. A renewable heating project at the Lancaster, PA, site allows for passing all exiting hood exhaust beside a closed-loop glycol system. The greatest energy benefit is that during the winter months, the warmer air exiting the building can be used to preheat the incoming air, which requires less energy from the steam boilers. Finally, efforts to move away from traditional landscaping towards the creation of spaces offering native landscaping that supports biodiversity and healthy habitats have resulted in a reduction of campus maintenance costs and water usage.

As operations grow, energy demand

increases. While a broader renewable energy purchasing strategy is still being determined for BPT operations in the US, actions are being taken to transition fleet vehicles to electric vehicles where possible, install smart energy systems (automated lighting/sensors, fume hood monitoring, and HVAC optimization), and ensure preventative maintenance procedures are in place to guarantee optimal functioning of freezers and refrigerators. Investment in Renewable Energy Certificates to offset a percentage of electricity usage with renewable energy sources is another decarbonization effort.

Adding employees increases resource consumption—but also creates opportunities. BPT-NA sites facilitate sustainable hiring practices and workplace culture by:

- Offering remote or hybrid work to reduce commuting emissions where feasible.
- Providing incentives for public transit, biking, or carpooling.
- Installing EV chargers on-site.
- Educating employees on sustainability practices (waste reduction, energy use, enhanced recycling, etc.).
- Partnering with My Green Lab to provide advanced educational opportunities for employees and laboratory certifications. Since 2024, three BPT-NA sites have completed seven My Green Lab certifications for eight departments.

Waste management is also a key area of focus for the business. Company-wide recycling programs are in place. In 2025, BPT Lancaster was the recipient of an Environmental Stewardship Award in the Corporate Sector by the Professional Recyclers of Pennsylvania (PROP) for the site's advanced recycling efforts. The business line is also encouraged to reduce single-use materials in the offices and operations and source consumables

from vendors who use sustainable materials and packaging. Currently, the first-ever regional business line sustainability challenge is in progress, partnering with [Fill It Forward](#) to reduce single-use waste across all of the North American sites and create meaningful global impact.

Another key aspect to managing sustainable growth across the BPT-NA sites is active measurement and tracking of our carbon footprint to identify areas

where we can eliminate and reduce our emissions. Related to this, all executive leaders have ESG goals that are tied to performance. This facilitates accountability and commitment from the top levels of leadership.

Moving forward, it will be important to continue to explore uses of technology to maximize the efficiency of our operations. Using AI and analytics to optimize logistics and reduce fuel use, automation/digitization of processes to minimize waste and monitor buildings in real time for efficiency will all be areas of focus. We truly believe that embedding sustainability into daily behavior, performance, and growth strategies is critical to the successful expansion and innovation of our business. For more information about Eurofins BPT-NA sustainability efforts, refer to our [2025-sustainability-report-final.pdf](#).

Big birthdays!

Eurofins BioPharma Product Testing in Lancaster, PA, celebrates 65 years of successfully delivering scientific solutions to clients, outstanding growth, and providing a great place to work for employees.

This year also marks a major milestone for **Eurofins Human Factors MD**, celebrating its **25th birthday!** Founded in 2001, HFMD was one of the first to focus exclusively on human factors evaluation and testing for medical products. Two and a half decades later, it remains committed to advancing patient safety and supporting our clients through high quality human factors research.

People are our chemistry

At Eurofins BioPharma Product Testing, our people are the most important element in our chemistry. Their dedication to quality testing, data integrity, and client satisfaction drive our success as an industry leader.

In this regular feature, we introduce you to some of the people who help clients deliver timely therapies and medical devices to

It's no surprise that Aiman Ahmad, Automation Engineer II, enjoys spending his spare time playing an open-world factory-building game centered on increasing efficiency through automation. For the past three years on BPT's Quality Engineering Team, Aiman has been laser-focused on elevating the client experience by increasing throughput, reducing errors and turnaround times, and strengthening data integrity. By closely shadowing laboratory processes, he methodically identifies opportunities to automate workflows in ways that benefit both clients and analysts.

Beyond engineering, Aiman gives generously to his community by volunteering at soup kitchens and supporting homeless groups and orphanages in Malaysia. Read more about Aiman:

What does your current job entail?

My role focuses on automating laboratory work-flows. I evaluate laboratory operations through direct observations and SOP reading to identify processes that are ripe for automation. Once identified, I lead the automation efforts for these projects, which may involve evaluating and sourcing off-the-shelf instrumentation, managing vendor-led



Aiman Ahmad, Automation Engineer II

custom build projects, or personally designing and developing custom solutions in-house.

What process improvements does your group initiate to serve clients better?

While our automation projects aim to maximize throughput and reduce turnaround times, our group's primary differentiator is a relentless focus on improving data integrity. We treat data security as a core design requirement by designing systems that automate data-entry work-flows to remove the risk of transcription errors.

By integrating our solutions directly with internal platforms, we ensure that client data remains secure, traceable, and untampered.

Why should clients trust us with their projects?

Our work is built on a foundation of human expertise. I see this every day. After reading countless SOPs, I have tremendous respect for the technical rigor and care our analysts bring to these complex, manual work-flows.

My goal is to act as a multiplier. By developing automation solutions that leverage our analysts' expertise, we empower them to be more efficient. This ensures that we are not just automating a process but enhancing our team's ability to deliver reliable, high-quality results for our clients.

Given all of your responsibilities, how would you describe a typical workday?

I divide my day into two sections to balance project oversight and

execution (the fun stuff). I dedicate the first half to the administrative side, which includes managing projects, documentation, ROI evaluations, and more. This ensures that our initiatives remain on track.

The second half is allocated for hands-on activities. This involves shadowing laboratory processes to identify bottlenecks and working in the Automation Laboratory to design, build, and iterate on our custom in-house solutions.

What kind of volunteer activities have you been involved with?

Whenever I return to Malaysia, I prioritize volunteering with local soup kitchens to distribute meals and engage directly with the homeless community.

I have also supported local orphanages by organizing interactive activities and collecting donations to help provide for the children – something I would like to get back into.

It is a small way to give back but seeing direct, positive impact is very important to me.

Building what's next in MedTech

Eurofins Medical Device Services welcomes EAG St. Louis Chemistry and Medical Device Testing Teams

The medical device industry is embracing an exciting new chapter of groundbreaking innovation and excellence, driven by the dynamic integration of top-tier expertise and expanded capabilities.

Eurofins Medical Device Services' integration of the St. Louis Chemistry and Medical Device Testing business units from Eurofins EAG Laboratories—effective May 1—positions the organization to elevate the standards of medical device testing, development, and regulatory support, ushering in a new era of innovation and excellence.

This strategic move underscores a shared commitment to advancing MedTech and delivering exceptional solutions to clients.

Eurofins Medical Device Services, recognized as a leader in comprehensive medical device testing and regulatory services, welcomes the highly respected



St. Louis teams into its network. The St. Louis facility, celebrated as a center of excellence for chemical characterization of medical devices, brings deep scientific rigor, technical depth, and a reputation for outstanding client service. In joining Eurofins Medical Device Services, the St. Louis teams will gain access to additional analytical platforms and cross-functional expertise, enhancing the ability to support product development, regulatory submissions, and ongoing quality programs. By integrating St. Louis capabilities, Eurofins strengthens its Biocompatibility Accelerator program, delivering faster, more predictable regu-

latory outcomes through end-to-end chemical characterization and biological safety alignment.

"This integration marks a pivotal step forward for our clients and our teams," said Mike Bond, President, Medical Device Services. "By uniting Eurofins Medical Device Services with EAG's St. Louis operations, we deliver broader expertise, faster innovation, and seamless support—empowering clients at every stage of the medical device lifecycle."

The transition, effective as of May 1, 2026 will be smooth and uninterrupted, ensuring that day-to-day operations, scientific staff, and client commitments continue as usual. Importantly, all other EAG Laboratories business units and service lines remain unchanged and will continue operating as part of EAG.

St. Louis Medical Device Testing is widely regarded as "best in class" for ISO 10993-18 testing, with more than 700 studies completed over the last several years. To date, all submissions using St. Louis data have been accepted by the FDA. The lab also offers particulate analysis as well as *in vitro* sensitization and irritation studies.

"By joining Eurofins Medical Device Services, we further expand our technical capabilities, accelerate innovation, and continue delivering the high-quality, science-driven solutions our clients expect, without disruption to projects or partnerships," Al Lee, PhD, Vice President of St. Louis Chemistry and Medical Device Testing, emphasized. "It's our people and our commitment to clients that made us "best in class" for ISO 10993-18 testing. Kevin Trankler, PhD, is our Senior Director and leads our scientists. Dr. Trankler has done an outstanding job listening to client needs, understanding the expectations of regulatory bodies, and delivering high quality work with our St. Louis Medical Device Test-



ing team." Dr. Lee added, "The St. Louis Chemistry team, which traces its roots to 1959 when the company was founded by Dr. Clara Craver as ChemIR, offers a large suite of investigative analytical testing for a wide range of industries, including medtech and pharma. We are very excited about this move."

The addition of the St. Louis teams strengthens Eurofins Medical Device Services' position as a solutions partner as it remains steadfast in its mission: to build what's next in medical technology, grounded in scientific excellence and client-centered innovation.

To learn more about the enhanced capabilities and the ways Eurofins Medical Device Services is building what's next in MedTech, visit www.eurofins.com/medical-device/testing/together-were-building-whats-next/ or contact your account manager for personalized guidance.

Global Expertise | Local Access | Proven Results

For more information on how we can solve your testing challenges, visit: www.Eurofins.com/BPT or: [Contact Us](#) to submit an inquiry.



**BioPharma
Product Testing**

© 2026 Published by Eurofins Scientific (Ireland) Ltd. All rights reserved. Eurofins, the Eurofins logo, are the trademarks of Eurofins Scientific Ltd. or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.