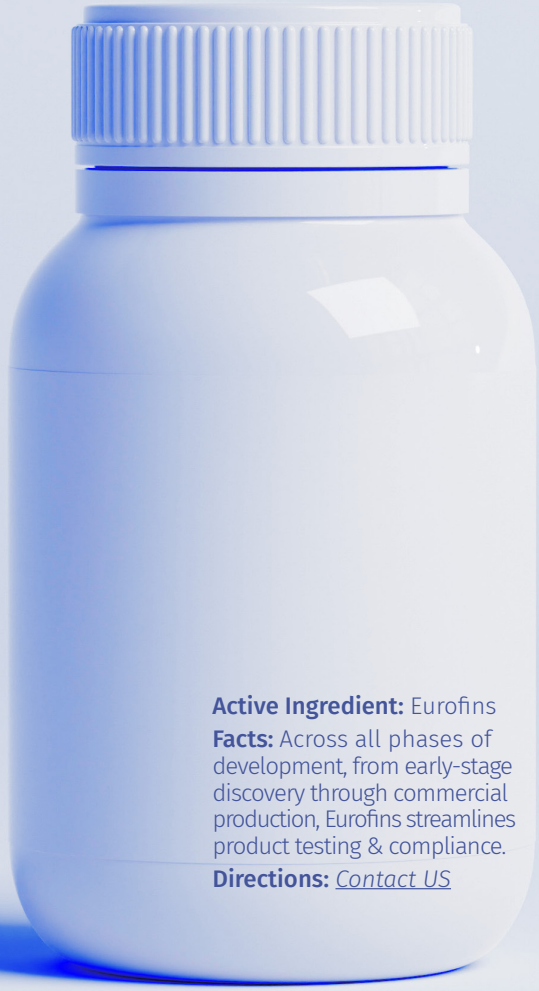
Bio/Pharmaceutical NEWS

Winter 2025

In this Issue



eurofins | BioPharma Product Testing

The chemistry of confidence: Eurofins BPT and your onshoring strategy

Brandon Scanlon, Sr. Vice President, Southwest, Eurofins BioPharma Product Testing

The onshoring imperative

The BioPharma industry is experiencing a significant shift toward onshoring manufacturing operations. Driven by supply chain resilience, regulatory alignment, and strategic investment, this trend is reshaping where and how products are developed and tested. For companies starting up new facilities, speed and reliability are critical—and Eurofins BioPharma Product Testing (BPT) is uniquely positioned to help clients succeed during this transformation.

Eurofins BPT advantage: A network built for scale

Eurofins BPT offers an unmatched footprint designed to meet clients where they are. With 15 facilities across North America, more than 2,300 employees, and over 800,000 ft^2 of laboratory space, our network is built for flexibility and speed. Our hub-and-spoke model ensures proximity for work that benefits from co-location. Key analytical testing hubs include:

- East: Lancaster, PA, and Research Triangle Park, NC
- Midwest: Columbia, MO, and Portage, MI
- West Coast: San Diego, CA, (significant expansion underway)

Beyond these hubs, we maintain operations in Jacksonville, FL; Crown Point, IN; and San Francisco, CA; with regional services in Houston, TX, and Cambridge, MA, – all locations aligned with emerging manufacturing clusters.

Eurofins BPT's NA footprint enables unparalleled regional coverage, flexibility, and responsiveness.

Solving client challenges: Speed, collaboration, and risk mitigation

Onshoring brings opportunity—but also challenges. Many clients tell us they lack resources to validate equipment, onboard staff, and maintain testing operations while focusing on manufacturing readiness. Talent shortages and time constraints only amplify these concerns.

Eurofins BPT solves these problems by:

- Accelerating timelines: Our proximity means faster turnaround and real-time collaboration. Co-location drives collaboration.
- Reducing risk: A distributed network with harmonized equipment, harmonized IT tools, and standardized processes ensure redundancy and continuity.
- Freeing client resources: We handle critical testing so clients can concentrate on getting new manufacturing sites operational.

Proven trust: partner with industry leaders

Our track record speaks for itself: 48 of the Top 50 Pharma Companies with a U.S. manufacturing presence already work with Eurofins BPT. This trust reflects our ability to deliver quality, compliance, and scalability at every stage of the product lifecycle.

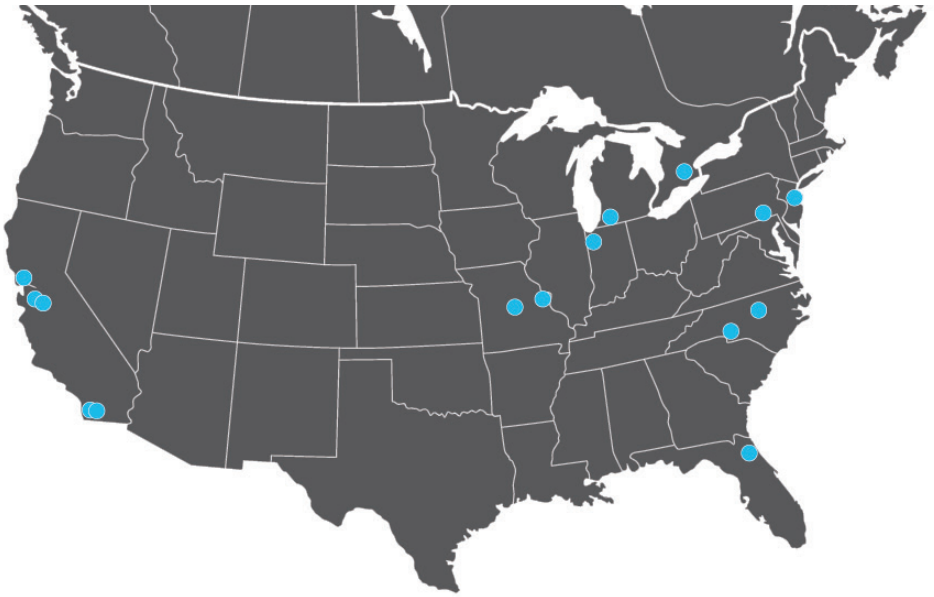
Ready to support your onshoring journey

As BioPharma companies make bold investments in U.S. manufacturing, Eurofins BPT stands ready to help you succeed.

To find out more about how we can support your onshoring strategies, contact your Eurofins representative or: *Contact-Us* to submit an inquiry.

Eurofins BPT - North America

- **15 Facilities in NA**
- **> 2,300 employees**
- **> 800,000 ft2 of laboratory space and growing**



Navigating USP 661.1 & 661.2: What new plastic packaging standards mean for the pharmaceutical industry

Monique Gray, Group Leader III, Pharmaceutical Raw Materials, Eurofins BioPharma Product Testing

Pharmaceutical products are vital to society to ensure a high level of patient efficacy and safety. Quality standards are required to ensure pharmaceutical deliverables, intended to serve public health, are suitable and appropriate. As per the United States Pharmacopeia (USP), a plastic packaging system intended to hold pharmaceutical deliverables can interact chemically with drug formulations and compositions, potentially impacting safety and performance.

The USP has introduced two new chapters, USP 661.1 and USP 661.2, both intended to improve the quality design process for the characterization of plastic raw materials and improve the quality assessment of finished plastic packaging systems.

For several years, USP <661> provided general guidelines for plastic packaging materials and systems. However, as materials of construction and packaging systems evolved, it became clear that the existing standards within <661> were no longer sufficient.

To address these gaps, USP 661.1 and 661.2 went into effect at the beginning of December 2025. According to the USP, those standards will introduce the following concepts:

- An established approach tailored to specific risk applications.
- Methodology enhancements targeted to improve the procedures related to physiochemical, biological, identification, and extractable testing for plastic raw material and storage systems.
- Enhanced analytical standards and specifications for plastic raw materials and plastic packaging.

This approach provides an enhanced mechanism to ensure the upmost quality and analytical assessment of plastic packaging, reassuring quality compliance and unadulterated pharmaceutical deliverables.

Key impacts to the industry:

- A qualified process for selecting suitable plastic raw materials based on pharmaceutical application.
- Updated methodology to enhance testing procedures and incorporate Total Organic Carbon evaluations.
- Integrated extraction temperature conditions suitable for various plastic packaging systems and components.
- A quality reassessment design for extractables and leachable protocols based on risk application.

How Eurofins empowers your plastic packaging compliance journey

Eurofins is a global leader in analytical testing and regulatory support for raw materials testing. Our end-to-end services help you navigate USP 661.1 and USP 661.2 with confidence. We are implementing the updated standards and already have these in place for clients who chose to adopt early the new USP standards.

Supporting USP 661.1: Plastic materials of construction:

We provide analytical support, expertise, and qualified instrumentation to meet the requirements of USP 661.1 through:

- Analytical testing across a variety of methods to support compliance.
- Comprehensive platform approach for characterization, identification, and quantification of elemental impurities.
- Biological testing to confirm material safety per USP <87> regarding material toxicity.

Supporting USP 661.2: Plastic packaging systems

We provide analytical support, expertise, and strategic guidance to help assess unique packaging system configurations to meet the requirements of USP 661.2 through:

- Direct collaboration with customers to ascertain a strategy to meet USP requirements and client expectations based on rationale and justification within the USP scope.
- Industry-targeted strategies built on USP foundations to test unique packaging applications.
- Customized Extractable and Leachable services tailored to your product and packaging system, that meet USP standards and are grounded in a risk-based approach.
- Capability to implement and support the biological testing components of the new USP standard.

These changes provide a holistic approach to USP compliance for manufacturers, packagers, and contract organizations worldwide.

Our experts collaborate to develop testing plans specific to the material in accordance with USP standards. By partnering with us, you'll streamline your transition to the new USP standards, safeguard product integrity, and be positioned to maintain uninterrupted market workflows.

For more information visit: *www.Eurofins.com/BPT* or: *Contact-Us* to submit an inquiry.

The challenging environment of biologics product development

Jon S. Kauffman, Ph.D., Senior Vice President, Biopharma Biologics, Eurofins BioPharma Product Testing

Biologics Product development can be quite a challenging landscape to navigate, and the process has evolved over these last five post-COVID years. Principally, the progression from early phase through commercialization has accelerated by quantum leaps. Expectations have changed; the conventional 10 to 15 year timeline is now compressed as sponsors sprint to deliver lifesaving/life-changing products to patients. Therefore, it is vital for biopharmaceutical organizations to choose partners like Eurofins Biopharma Product Testing (BPT) with the agility, flexibility, capacity and experience to support their chemistry, manufacturing, and controls (CMC) and commercial release testing needs.

This acceleration has led to a more risk-based approach to method establishment and resulted in the utilization of fit-for-purpose methods to monitor critical quality attributes (CQAs) throughout the first phases of clinical activities. These methods then need to be validated rapidly and thoroughly to support crucial Process Performance Qualification (PPQ) campaigns. Expectations of regulators from the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) continue to intensify, reflecting the guidance and recommendations of the International Council for Harmonization (ICH Q2 R2).

Late phase method validations have become much more complex and extensive. For example, assays for monitoring critical CQAs, such as low and high molecular weight impurities, need to be evaluated for linearity, precision, accuracy, limit of detection (LOD), and limit of quantitation (LOQ) for these species. This necessitates multiple linearity studies, including dilutional linearity, co-mixed with forced degradation material linearity and low-level linearity for each species. In addition, formulations and concentrations are sometimes only finalized entering pivotal Phase III studies, further influencing method establishment strategies and timelines.

Eurofins BPT partners with our clients through consultative discussions to develop strategies and protocols to accomplish these objectives in the most time and cost-effective manner.

Analytical equipment and software vendors also continue to develop more sensitive and powerful tools at a faster pace. There are an increasing number of antibody-drug conjugates, viral vector products, and fusion protein candidates in the pipeline. As modalities become more complex, the technology required to evaluate their CQAs and characteristics must evolve as well.

However, this can be problematic in a Good Manufacturing Practices (GMP) environment where change control must be managed. Key instrumentation platforms and software can quickly become obsolete, or their support can be discontinued. This is of concern when methods have already been filed with specific equipment and technology, and bridging studies may be needed. Therefore, method lifecycle must be carefully considered. As with method validation, Eurofins BPT interfaces with our clients and vendors to perform risk assessments on the methods, including the required instrumentation, reagents, consumables, software, etc.

The fact that multiple Contract Manufacturing Organizations (CMOs) may be utilized by the sponsor can further complicate logistics. Flexibility and capacity are key to accommodating manufacturing shifts. In some cases, sponsors prefer proximity to the manufacturing site and/or redundancy of testing laboratories.

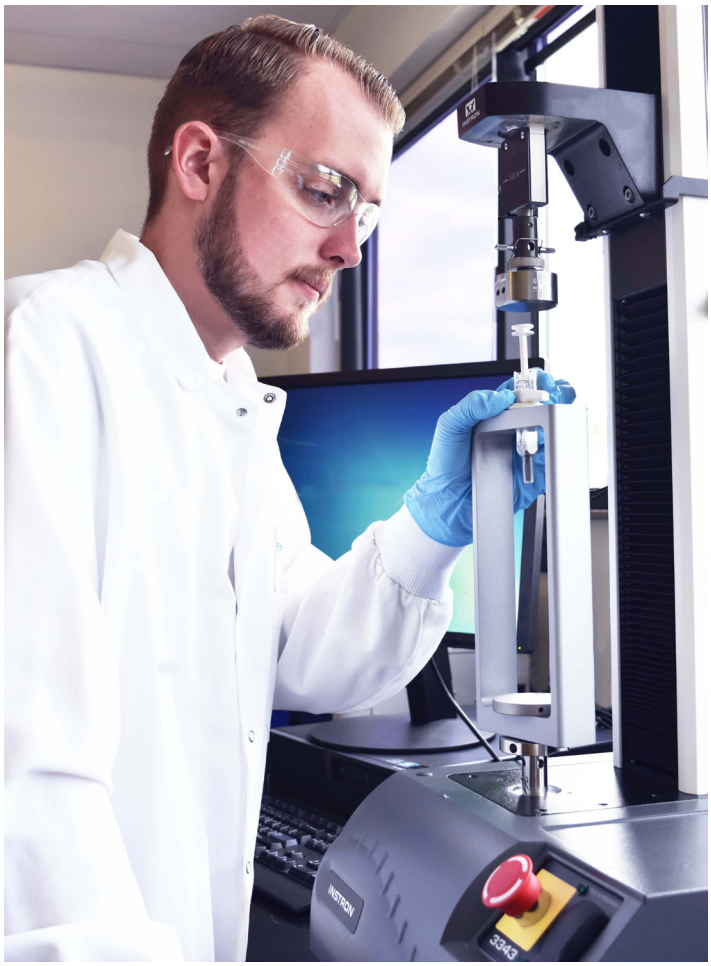
Eurofins BPT's harmonized network of laboratories across North America with full-service biologics capabilities in Lancaster, PA, and Columbia, MO, and capabilities in San Diego, CA, and Portage, MI, positions us well to overcome the logistical challenges that are inherent to bioprocess manufacturing and biologics product testing.

For more information visit: *www.Eurofins.com/BPT* or: *Contact-Us* to submit an inquiry.

Eurofins ensures combination drug, device & delivery systems meet regulatory and patient safety requirements

Ashley Harger, Consulting Operations Strategist, Eurofins Medical Device Services

The biopharmaceutical industry has delivered an increasing number of biologics to the market with advances in the development of targeted treatments, effective engineering processes, and positive impacts on patients.



While needle-free injection devices are being explored as alternative delivery methods, the use of pre-filled syringes, manual injector pens, and auto-injectors remain as the most reliable administration methods, allowing patients the option for self-injection.

Efficacy of pre-filled syringes, manual injector pens, and auto-injectors is established with suitable functional testing to demonstrate reliable delivery of the drug to the patient. The convenience of self-injection means that the delivery device will be managed by the patient themselves through everyday life, being handled much more than products that are administered in a clinic or hospital setting.

Throughout both the device and packaging design, it is critical to evaluate the function under stressed conditions.

Functionality tests are performed at various stages of the product life cycle to establish confidence in the design of the device and the packaging to verify that the device and packaging can protect the drug and delivery device so it will remain effective for patient use.

Early phase testing also evaluates consistency in manufacturing with critical measurements or dimensions of the needle or other components of the device. Eurofins conducts testing that includes dimension analysis.

For biological extracts, recombinant products, vaccines, cell and gene therapies, Eurofins supports testing beyond the analysis of the therapeutic. Our Medical Device Package Testing team supports studies for Design Verification of the delivery device as well as the packing, including all layers of packaging - all the way to the outermost layer, and with transit testing.

To conclusively evaluate the design prior to initiation of the manufacturing and packaging processes, transit testing, along with package integrity testing, barcode and label verification, and functional testing of the device provide confidence in the design of both the device and the packaging.

For these combination products, a typical design verification study will evaluate for temperature excursions followed by testing that demonstrates sterility, either with microbiological testing or container closure integrity testing. Additional exposure of product is simulated with drop or vibration of individual units, followed by functional tests to demonstrate accurate dose delivery.

Support for shelf-life studies also demonstrates product efficacy throughout the product expiration by comparison of real-time aging with accelerated aging conditions. Eurofins offers a variety of aging conditions to perform shelf-life studies.

Eurofins is a leader in testing combination products with more than a decade of experience. By integrating container closure integrity studies with device functionality evaluations, Eurofins generates combined evidence, demonstrating sterility, stability, and usability under storage, aging, and distribution to safeguard both drug and device performance. This dual approach anticipates the expectations of regulators, who increasingly view container closure and device packaging as interdependent elements of patient safety.

In addition to technical testing, Eurofins supports regulatory and post-market needs. Consultants collaborate to design packaging validation plans aligned with ISO, ASTM, ISTA, FDA, and EMA expectations, building evidence strategies that withstand review. Post-market, Eurofins assists with packaging changes, safety labeling updates, shelf-life extensions, and MDR compliance activities, supporting continued packaging effectiveness and compliance throughout the product lifecycle.

...Eurofins generates combined evidence, demonstrating sterility, stability, and usability under storage, aging, and distribution to safeguard both drug and device performance.

For more information visit: *www.Eurofins.com/BPT* or: *Contact-Us* to submit an inquiry.

Across all phases of drug development, great science starts with great collaborations

Heather Bridwell, MS, Director, Pharmaceutical Product Testing, Eurofins BioPharma Product Testing

Eurofins BioPharma Product Testing (BPT) has an expansive suite of analytical and regulatory support services for small molecule pharmaceutical programs. Our integrated expertise, advanced instrumentation, and agile operations help clients achieve successful outcomes across all phases of development, from early-stage discovery through commercial production. Whether supporting a single study or managing a complex, multi-phase program, our team is committed to delivering high-quality, compliant, and timely results.

Great science starts with great collaboration

Scientifically sound and robust analytical methods are the backbone of any successful pharmaceutical testing program. We believe great science happens through collaboration. Each project is supported by dedicated technical leads and project managers who ensure transparent communication and alignment with regulatory and program specific goals.

Whether developing new methods, adapting existing ones for different dosage forms or matrices, or onboarding your in-house procedures, our approach is flexible and tailored to your needs. While scientific integrity and high-quality work are non-negotiable, we know cost matters, too. Our teams are always looking for practical ways to deliver value.

Reliable stability storage that meets your needs

Stability testing is a cornerstone of pharmaceutical development, providing critical data to support product shelf life, storage conditions, and regulatory submissions. We provide GMP-compliant onsite stability storage across all ICH conditions, various non ICH conditions, and can custom configure chambers to meet clients' specific needs. All chambers are continuously monitored, redundantly supported, and fully validated to ensure sample integrity and regulatory compliance.

Stability testing on track and on time

Meeting stability window testing requirements is critical to maintaining regulatory confidence and ensure data readiness for submission. Our dedicated stability team is focused on pulling samples on time, using automated scheduling, proactive resource planning, and robust tracking tools. Our analytical teams rely on streamlined workflows and close cross-functional coordination to complete testing within protocol timelines to deliver high quality results on time.

Faster insights with accelerated stability assessment program

In today's fast-paced pharmaceutical environment, traditional stability studies can impede timely decision-making. Accelerated Stability Assessment Program (ASAP) employs validated predictive modeling to estimate long-term stability outcomes based on short-term data generated under elevated temperature and humidity conditions. By applying kinetic modeling to degradation pathways, product shelf life and optimal storage conditions can be projected within weeks rather than months. We are actively expanding our capabilities to support ASAP studies with new services expected to be operational by mid-2026.

Flexible operations to meet evolving program needs

Every small molecule pharmaceutical program is different, and we've built our operations to flex with your needs. When timelines shift or project demands grow, we move quickly. By scaling staffing, instrumentation, and workflows we keep your program moving forward without interruption. One of the reasons we can respond so quickly is our strong internal training and onboarding program. We invest in developing our team from day one, ensuring new staff are equipped with the technical skills and regulatory knowledge needed to contribute confidently and effectively. This means we're able to ramp up support fast without compromising quality or compliance.

A true partnership approach

At Eurofins BioPharma Product Testing, we strive to build our client relationships like a partnership, and we are passionate about finding ways to make your programs successful. We don't believe in simply being a vendor, rather we provide an extension of your team that is as invested in your program's success as you are. From new program startups, through regulatory submission, and into commercial production, **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.

Software upgrades, data integrity, and data security – oh my!

Daryl Krushinsky, Senior Director Operations OUIT Solutions, Eurofins BioPharma Product Testing

The quote, "Lions, and tigers, and bears, oh my," was made famous by Dorothy, the Tin Man, and the Scarecrow while walking through a dark forest in *The Wizard of Oz*. It was used to express fear and anxiety about unknown dangers and is often used now to refer to daunting (or scary) tasks that we encounter. These feelings resonate as headlines remind us of evolving IT security threats and constant IT breaches across the globe. We know that we must continuously improve and upgrade laboratory data systems to stay ahead of these new data integrity and data security threats, however, we must also do so in a controlled manner within the heavily regulated biopharmaceutical environment.

Hackers utilize many tools to gain entry into company networks. Falling victim to a simple phishing scam can provide them with just enough access to gain necessary credentials to overtake a network and/or plant malware or ransomware. The Eurofins approach to mitigate this risk is twofold. First, we require on-going and in-depth IT security training for every employee to increase their awareness and vigilance. Second, technological controls minimize risk by detecting unusual activity and by limiting access across the network. Training programs are relatively easy to implement, but changing behavior is a bit more difficult. Harder still, is ensuring that technology remains current in a regulated industry.

The basis for implementing technological control for detection and minimizing access risk is to ensure that all networked laboratory system computers and servers remain on currently supported Windows Operating System (OS). This ensures that they remain supported and continue to get upgraded security patch releases as new threats emerge. Upgrading the OS may often require an upgrade to the existing instrument software application to ensure ongoing compatibility and proper functionality. This can then also necessitate upgrade or replacement of the instrument itself – oh my!

Rather than following the Yellow Brick Road, the team at Eurofins navigates these changes with a robust and well-established change management program to make the journey less daunting. There is no shortage of enhancement and implementation projects to improve data integrity and data security efforts. A few select highlights are included below:

- **Softmax® Pro Enterprise software** is currently being tested and validated for implementation in late 2025 and will manage the fleet of plate readers at Eurofins. This version will centralize system administration efforts to provide greater control over previous stand-alone software versions. Also, the enterprise version utilizes a database to enhance data security and integrity by eliminating the prior flat-file structure. Additionally, this version incorporates the use of electronic signatures to improve integrity of data analysis and review workflows.
- **LabSolutions™** is an additional enterprise level software being implemented to manage a new series of UV/Vis detector. Once fully validated, LabSolutions will permit the phase-out of two related software systems and associated detector hardware that are outdated and are not compatible with current computer and server OS requirements. As noted previously, current and supported Operating Systems are required to ensure continued security patching to detect new threats.
- **Kneat® software** has been in use within Eurofins for several years. The system provides a paperless process with electronic signature capability. It automates laboratory instrument validation with a "poka-yoke" process by providing prompts for required inputs to improve compliance. Kneat has recently undergone change control to modernize the underlying structure, which permits continued system improvements and compatibility with future OS upgrades and patching.

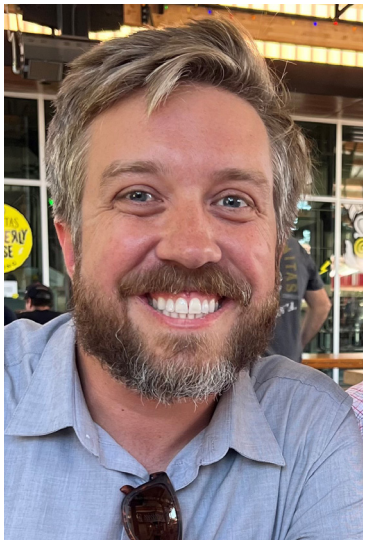
Eurofins continually mitigates the numerous challenges with maintaining laboratory systems that provide accurate results AND remain secure and compliant in the face of new threats. There is no need to worry about the "dark forest" of computerized system upgrades at this trusted contract laboratory. Whether it's adding the newest technology or updating current systems, Eurofins is committed to supporting our clients with a proactive approach to laboratory system data integrity and data security.

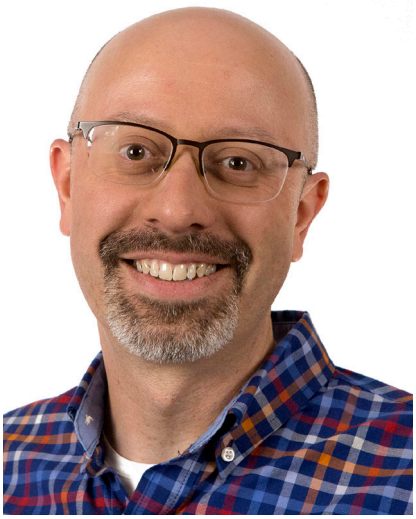
For more information visit: *www.Eurofins.com/BPT* or: *Contact-Us* to submit an inquiry.

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 patients and make the world healthier and safer.





BPT's West Coast dynamic duo Dylan Kimball and Paul Lightner, are leading microbiology testing and chemistry testing services, respectively, at our San Diego and Petaluma, CA, sites.

Dylan Kimball, Director of Microbiology, BPT San Diego and Petaluma, CA, brings a decade of experience in microbiology and analytical chemistry testing for pharmaceutical manufacturing clients. As Eurofins BioPharma Product Testing's network of laboratories continues to expand across North America, offering an East to West Coast "local" laboratory experience is essential to microbiology clients, where proximity matters.

"As we continually improve service solutions across our network, we are integrating laboratory systems, aligning test codes, sharing best practices, and blending the ethos of Eurofins to deliver seamless, value-driven solutions to clients," Dylan said. "In my previous roles, I sent samples to Eurofins and was aware of its good reputation, and during my extensive interview process, I was able to peek behind the curtains and was impressed with how Eurofins is great at identifying and developing top talent to serve clients well and is so successful." Read more about Dylan:

What does your current job entail?

I lead the microbiology sites for Eurofins in San Diego and Petaluma. These were part of the Infinity Laboratories acquisition in 2024. I think the most important aspect of my job is to foster and strengthen the integration of these micro sites into what had historically been a very chemistry-focused entity. With experience running both chemistry and microbiology third-party labs, I am eager to see these operations building off and strengthening one another to improve our service portfolio to be a comprehensive offering for our clients.

What is the scope of your group?

Our group delivers comprehensive microbiology solutions for biopharma clients—covering raw materials, drug substances, drug products, and some medical devices. We confirm manufacturing hygiene and product sterility through services like environmental monitoring, bioburden and microbial limits testing, sterility, endotoxin, mycoplasma, and microbial identification. Essentially, we provide confidence to clients that their products can be manufactured safely from early development through commercialization.

Why should clients trust us with their projects?

Clients trust us because Eurofins has a proven reputation for quality and compliance, and we build on that with a collaborative, local approach. By establishing microbiology sites in Southern California and the Bay Area, we give West Coast clients easier access for audits, face-to-face meetings, and rapid testing—accelerating communication and trust. We're not reinventing Eurofins' success; we're applying it at a more local, tailored level, combining global expertise with regional presence to be both reliable and accessible.

How does your group's work impact/benefit society?

The job of the micro lab is to provide confidence in the quality and safety of manufactured products. In the BioPharma Product Testing business, that feels even more impactful, as the products we are helping to safeguard are intended for those most at risk, and often most vulnerable to infection.

Paul Lightner, Senior Director, Routine Testing, Eurofins BPT San Diego, CA, grew his career for 18 years at BPT's Columbia, MO, site, honing expertise in chromatography, spectrophotometry, electrophoresis, and compendial assays—starting with small molecules and expanding into biologics, such as monoclonal antibodies, antibody-drug conjugates, fusion proteins, and vaccines--all while growing regulatory knowledge across GLP and GMP frameworks.

Earlier this year, Paul relocated to San Diego, CA, where he's applying his eLIMS expertise to strengthen the site and deepen his understanding how the broader BPT North America network can better serve clients. "Following my transition to BPT San Diego, I've continued to champion cross-functional collaboration—bringing experience in leading support groups and fostering strong interdepartmental connections," says Paul. "My approach is grounded in developing people, but reinforced by a broad understanding of eLIMS systems, quality priorities, and data-driven decision-making. I'm passionate about aligning metrics with meaningful outcomes and ensuring our analytical testing services reflect both scientific rigor and operational excellence." Read more about Paul:

What does your current job entail?

My role centers on communication and aligning internal resources with client needs. I'm passionate about developing leaders, solving problems, and streamlining processes to better serve our customers. By fostering a collaborative environment and setting aspirational goals, we empower employees at all levels to share best

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Eurofins expands compendial container and packaging testing capabilities with new autoclave

Heather Cawley, Principal Scientist, Pharmaceutical Raw Materials, Eurofins BioPharma Product Testing

Meeting the rigorous demands of compendial autoclave testing presents a unique set of challenges for pharmaceutical laboratories. From ensuring precise control over sterilization parameters for various size containers, to maintaining compliance with global pharmacopeial standards, laboratories must navigate complex technical and regulatory requirements to deliver reliable results. At Eurofins, we understand these challenges firsthand.

Eurofins brings more than two decades of expertise, testing various pharmaceutical containers, elastomeric closures, and packaging systems per USP, EP, and JP requirements. We're proud to announce we are integrating the Systec® HX-320 autoclave into our laboratory operations.

This advanced autoclave will enable us to perform container testing in complete alignment with compendial requirements. The HX-320 offers programmable cycles and precise control over temperature, pressure, and cooling which are essential for achieving consistent and accurate results.

To ensure optimal performance, the system will undergo extensive Performance Qualification (PQ) activities across a wide range of autoclave loads and cycle programs. It is also equipped with 21 CFR Part 11 compliant software and robust data integrity controls supporting regulatory compliance. This enhancement reflects our continued commitment to delivering high-quality, dependable testing services to the pharmaceutical industry.

As we continue to make progress on installation and qualification activities, Eurofins is targeted to offer testing services with the Systec HX-320 in early 2026. If you have upcoming container testing needs or questions about how our team can support your project, we encourage you to: *Contact-Us*.

People are our chemistry

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practices and drive performance. I focus on building meaningful connections—across teams, sites, and client programs—to help people achieve their goals.

What is the scope of your group?

The Routine Testing Department at San Diego encompasses two FTE programs and nearly 20 additional smaller client programs. We support analytical testing of therapies encompassing gene editing and mRNAs, monoclonal antibodies, PEGylated peptide conjugates, small molecules, and gel contraceptives. My responsibilities additionally include the Materials/Facilities Department, who ensure client materials are handled, stored, and dispositioned with traceability and attention to detail. Together, we maintain a lab environment that's safe for employees, showcases our capabilities for clients and auditors, and focuses on efficiently executing testing for clients. Our analytical support includes characterizing materials, developing methods that withstand regulatory scrutiny, and using those methods to monitor the stability profile of life-changing therapies over time.

Why should clients trust us with their projects?

We have the technical expertise and commitment to quality to help our clients make informed decisions regarding their products. Our site is regularly audited and consistently performs well under inspection, highlighting the robustness of our procedures. We constantly strive to anticipate client needs and exceed their expectations as an analytical partner. Whether they are early in the drug development process, or have commercial product on the market, we're able to tailor our offerings to their unique requests.

How does your group's work impact/benefit society?

We're verifying the safety and efficacy of drug products that have the potential to transform lives. These include pharmaceuticals in clinical trials and on the commercial market aiming to address rare diseases, improve cardiovascular health, combat kidney disease, treat COVID-19, prevent eye disease, and fight various forms of cancer. Where there are patients in need, we partner with our clients to make a positive impact for the future.

For more information on how we can solve your testing challenges, visit: *www.Eurofins.com/BPT* or: *Contact-Us* to submit an inquiry.

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