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News
BIO/PHARMA - MEDICAL DEVICES - COSMETICS

Extractables LC/MS Search Engine offers a novel database for E&L identification

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Screening materials and medical products for compounds that may present a risk to health and safety is precisely what Extractables and Leachables (E&L) testing delivers.

Nevertheless, the system under testing is often complex enough to ensure that a different “blend” of compounds will emerge, resulting in a degree of uncertainty during the identification process.

The recurrence of tested items allows recovering of previous characterisation, increasing the efficiency of the identification workflow, reducing errors, and improving the skills of the team. This is crucial when aiming for continuous improvement and easier data sharing between those involved in the process. This makes the accumulated experience one of the most valuable assets in E&L testing, especially for the HPLC/Q-TOF technique, based on hundreds of characterisation studies and resulting in a considerable amount of extractable profile data. The challenge became: how do we manage these large data and ensure that the relevant information is quickly available when needed?

A collaboration between Eurofins BioPharma Product Testing Italy and *The Visual Agency s.r.l.*, a web design data-driven company based in Milan, resulted in a novel tool for E&L identification, the Extractables LC/MS Search Engine or *ELSE* – a customised web application that allows rapid search of LC/MS results among hundreds of studies performed over the years. Filtering by exact mass, retention time and polarity, ELSE points directly to the relevant information while optional parameters can be used to refine the search. This new tool available for the Eurofins E&L teams strengthens the characterisation capabilities, helping customers reach their goal of achieving the ‘total compounds identification scenario’ requested nowadays by the regulatory bodies in the E&L studies. For more information, visit: *https://www.eurofins.it/packaging-and-devices-testing/extractables-leachables*

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New FDA Guidance: Screening for Diethylene Glycol and Ethylene Glycol Contamination

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Since the notorious sulfanilamide elixir diethylene glycol poisoning of 1937, which resulted in over a hundred deaths, and the subsequent enactment of the FD&C Act in 1938, the modern U.S. Food and Drug Administration (FDA) has been monitoring poisoning incidents in the U.S. and abroad. However, despite decades of modernisation efforts for high-risk drug components monographed in the United States Pharmacopeia (USP) and the inclusion of chapter <469>, numerous deaths have still been documented globally as a result of contaminated products with not only DEG but ethylene glycol (EG). Both DEG and EG largely make their way into products via poor manufacturing practices of raw materials or contamination of solvents and excipients used in production. Consequently, in May 2023, the FDA published Guidance for Industry: Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol.

FDA guidance recommends testing all containers of many high-risk materials, including some polyethylene glycols, polysorbates, sugar alcohols, fatty acid oils, and nonionic surfactants used as excipients. While several of these materials are monographed with DEG and EG specification limits or are captured in the general chapter, the USP list is not yet all inclusive.

Eurofins' core mission is to contribute to a safer and healthier world by providing customers with innovative and high-quality laboratory, research and advisory services. To that end, Eurofins BPT has established a fast, high-quality and robust approach to monitor these high-risk components for DEG and EG according to USP <469>, for not only the monographed materials, but any material that presents a risk to patient safety. By using the Eurofins Platform Approach, not only can materials in USP <469> be accepted for rapid GMP testing, but a turn-key service for non-monographed materials is ready to go at a moment's notice to validate the method. The Eurofins BPT Raw Materials laboratory in Lancaster, PA, is one of the largest single raw material laboratories in the world, with a network of companion laboratories in North America and abroad designed to deliver fast and reliable quality control testing to our customers. Eurofins provides a one-stop-shop for full GMP raw material testing covering chemistry, biochemistry, microbiological and viral services. To learn more, *Contact Us*.

Platform methods validated at Eurofins BPT: the future for ATMP analytics

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Advanced Therapy Medicinal Products (ATMPs) define a broad category of complex and innovative biologics, which encompasses tissue, cell-based and gene therapy products.

These revolutionary medicines offer groundbreaking new opportunities, addressing unmet medical needs for rare and complex diseases. Among these, high costs and resource demands pose significant hurdles, especially in the transition from bench to bedside, when the demand for validated assays and GMP requirements must be fulfilled.

The Eurofins BioPharma Product Testing (BPT) network of laboratories is acutely aware of the challenges our customers face in this sector. To offer support, our experts, comprised of Biologists, Biotechnologists and Analytical Chemists, have been active for several years in testing ATMPs. Eurofins BPT offers a complete package of services to address their needs, including safety, characterisation, and identity for ATMPs.

In particular, Eurofins BPT Italy has recently expanded its staff with the aim of having a dedicated team for the development and validation of the platform's methods. This approach is considered crucial due to the nature of cell and gene therapy products, which present several challenges, such as short product shelf life and limited batch size. Most recent implementations at our Italian site, for instance, include platform methods supporting Residual Plasmid DNA, Residual E1A DNA, Residual LTA DNA, Replication Competent Lentivirus (RCL) on drug products and Vector Copy Number (VCN).

Eurofins BPT is investing in platform methods to provide a broader package of services and is continually active in the validation of new ones, with a packed pipeline. The proposed platform approach aligns with Eurofins' commitment to promoting the sustainability and affordability of Cell/Gene Therapies, supporting clients to meet regulatory requirements through all phases of assay development/validation, as well as routine testing when needed. For more information visit: *https://www.eurofins.it/biopharma/* or *contact us* to learn more.

Eurofins CDMO Alphora announces completion of a new pilot scale biologics development facility

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In an unwavering commitment to being collaborative partners in life-saving therapy development, Eurofins CDMO Alphora Inc. has seamlessly integrated existing experience in API and HPAPI with robust biologics capacity at the completion of its biologics pilot scale facility.

Facility highlights:
Spanning 3,300 square feet in Mississauga, Canada, capabilities at the pilot biologics facility include analytical services, upstream & downstream development, process design and gap analysis, process scale up, bioassays, and cGMP quality documentation. The facility uses mammalian cell culture for the production of therapeutic proteins and mAbs, as well as the use of other feedstocks, including transgenic plants, transgenic milks, and plasma. Leveraging advanced technology, Eurofins Alphora's facility adeptly manages diverse batch sizes. With 200 L fed-batch and perfusion capabilities, the biologics laboratories can meet large-scale projects.

Expansion and growth:
Supported by a skilled team and state-of-the-art equipment, the facility optimises timelines in manufacturing biologic drug candidates. Furthermore, numerous new bioassays and protocols have been added across cell-based functional and binding assays. With advanced separation techniques for enhanced process performance, Eurofins Alphora is well suited to be your CDMO partner to fast track your product to market.

Integrated ADC Services:
By consolidating our deep expertise in linker and warhead development with our new biologics manufacturing capacity, we now offer an end-to-end solution for antibody drug conjugate (ADC) production, all under one roof. For more information, visit: *www.eurofins.com/biopharma-services/cdmo/eurofins-alphora/* or *Contact Us*.

Eurofins' new Clinical Trial Supplies makes the complex simple

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As a new business unit within the Eurofins network of companies, the Clinical Trial Supplies purpose-built cGMP facility in Horsham, PA, US, offers primary and secondary packaging, labelling, QP services and global distribution of Investigational Medicinal Products (IMP), as well as Advanced Therapy Medicinal Products (ATMP) in support of phase I to phase IV clinical trials. The opportunities and synergies this facility will bring to BioPharma clients is profound.

Built from a blank canvas by a team of industry veterans, the operations, processes, and IT systems were designed to offer exceptional service levels with fast turnaround times, beating the current industry standards: On-demand Packaging and Just-in-Time Packaging. By deploying a global Enterprise Resource Planning (ERP) solution from day one, these new services are "Agile by Design" with a superior quality mindset to begin helping patients globally.

Further capabilities include labelling services, getting the right drug to the right patient, taking into account randomisation and blinding in complex and adaptive clinical trial protocols, decentralised clinical trials support (direct to patient), comparator sourcing and schedule I-V, and controlled substance storage services.

A clinical trial cannot run without the drug on time – patients are always our focus

This remarkable addition to the Eurofins network of companies marks a significant step forward in our commitment to excellence and innovation. This facility is more than just an addition; it is an expansion of our global footprint and collaboration with the Eurofins CDMO network of companies, and a testament to our dedication to delivering quality clinical trial solutions efficiently and consistently. For more information, visit: *https://eurofinscentrallaboratory.com/clinical-trial-supplies/*

Eurofins Discovery accelerates Target Protein Degradation drug discovery

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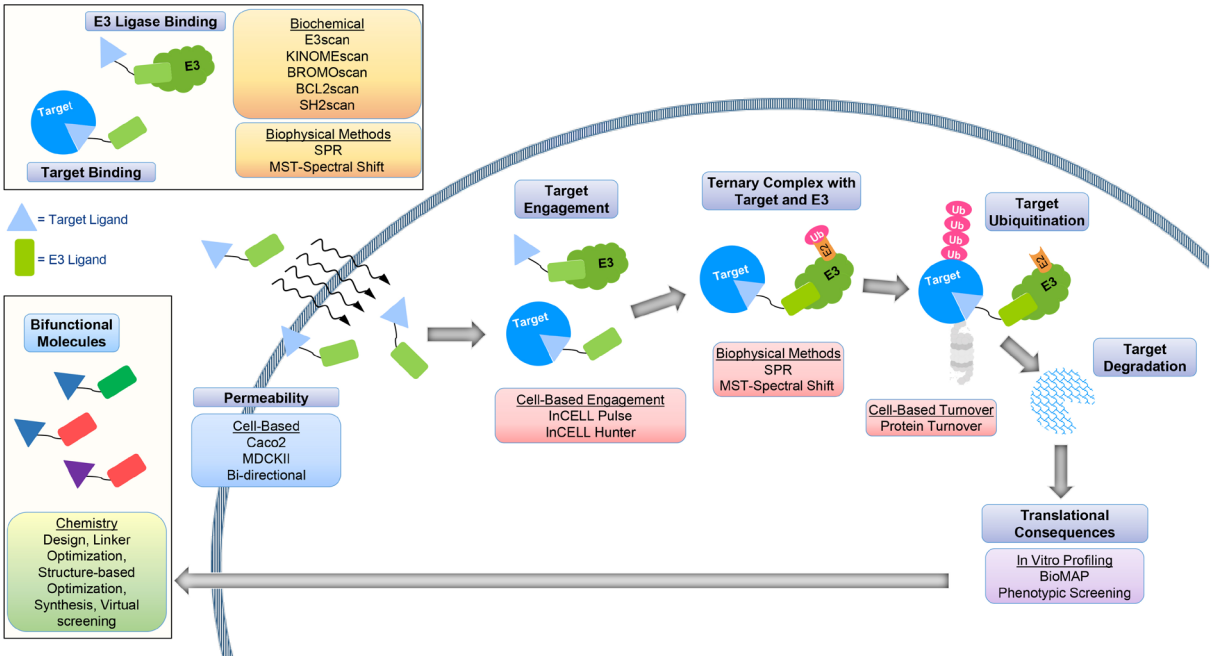
Eurofins Discovery, a global leader in providing drug discovery and development solutions, has built a comprehensive toolbox of capabilities to enable programmes in the Targeted Protein Degradation field. With wide-ranging applications for Molecular Glues and PROTACs® (Proteolysis Targeting Chimeras) spanning multiple therapeutic areas, such as oncology, neurodegenerative diseases, and beyond, these approaches hold promise for targeting notoriously challenging proteins that were previously considered "undruggable," and offer new avenues for treating diseases with enhanced precision and reduced side effects.

Eurofins Discovery's advanced capabilities in developing Molecular Glues and PROTACs® integrates computational, medicinal and automated synthetic chemistry, molecular and cellular biology, and pharmacology. As a case study, this process is being applied to generate PROTACs targeting the PIM3 kinase and includes:

- Medicinal chemistry-driven precision design of PROTACs® based on known PIM inhibitors as well as hit compounds obtained from an internal HTS campaign.
- Use of a state-of-the-art robotics lab that accelerates PROTAC® preparation by enabling the simultaneous synthesis of multiple compounds in parallel.
- Characterisation and validation of novel PIM3 bifunctional degraders using KINOMEscan®, KinaseProfiler™ and E3scan™ platforms to assess potency and selectivity.
- Use of biophysics methods like Surface Plasmon Resonance (SPR) or MicroScale Thermophoresis (MST) to assess binary (PIM3-PROTAC®) and ternary (PIM3-PROTAC®-E3 ligase) complex formation, as well as establishing the key interaction parameters between PROTACs® and their target proteins, such as the affinity, binding kinetics, residence time and cooperativity factor.
- Cellular assays assessing quantitative protein degradation and translational phenotypic assays (including the BioMAP® and OncoPanel™ Platforms) evaluating pharmacological effects in human cells, determining cellular efficacy, and directing potential clinical applications.

These cutting-edge capabilities in Targeted Protein Degradation positions Eurofins Discovery as an ideal collaborator for biotech and pharma partners aiming to develop novel treatment approaches, offering hope for innovative therapies that significantly impact patient care. For more information, visit: *www.eurofinsdiscovery.com*



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