eurofins | BioPharma Product Testing

EUROPEAN NEWSLETTER

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ENVIRONMENTAL RISK ASSESSMENT IN THE PHARMA SECTOR: NAVIGATING REGULATORY FRAMEWORKS AND IMPLEMENTATION STRATEGIES

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What is ERA? The Environmental Risk Assessment (ERA) evaluates the potential impact of a medicinal product,primarily its active substance and relevant metabolites, on the environment following patient use and disposal. It considers factors such as persistence, bioaccumulation, and ecotoxicity to ensure that medicines are developed and marketed responsibly, minimising environmental risk.

The ERA of medicinal products is now a key regulatory requirement for all marketing authorisation applications (MAAs) in Europe. With the implementation of the EMA's revised guideline (Rev. 1, effective from 1 September 2024), the pharmaceutical industry faces a heightened expectation to demonstrate not only the safety and efficacy of products for patients, but also their environmental impact.

The new framework strengthens obligations across all product types — including generics — and places a particular focus on antibiotics, hormones, endocrine-active substances (EAS), and cytotoxic agents, due to their potential environmental persistence and biological activity. Regulatory authorities are already issuing deficiency letters requesting updates or additional data where previous ERA submissions do not align with the new standards.

In this evolving landscape, companies must act proactively. The ERA may need updating in the event of significant changes (e.g., dosage, indication, patient population) or increased environmental exposure. For both new and existing MAAs, a structured testing strategy is essential to ensure compliance while avoiding unnecessary studies and costs.

Eurofins BioPharma Product Testing supports pharmaceutical companies through dedicated consultancy services:

- Gap analysis of existing ERA documentation against the new guideline.
- Definition of a testing strategy that identifies only the studies truly required.
- Preparation or update of ERA dossiers (Phase I and Phase II), including risk mitigation measures and labelling recommendations.
- Expert regulatory insight based on direct feedback from EMA and national agencies, ensuring dossiers are built to meet current expectations.

By combining scientific expertise and regulatory know-how, Eurofins BioPharma Product Testing provides a one-stop solution, from document preparation to laboratory execution, leveraging its extensive network of GLP-compliant testing facilities to perform the full range of required studies.

For more information visit: www.eurofins.it/consultancy-services/biopharma/environmental-risk-assessment-for-medicinal-products-for-human-use/

CASE STUDY: SOLVING A COMPLEX ASSAY CHALLENGE IN INHALATION PRODUCT TESTING

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Inhalation pharmaceuticals demand exceptional analytical precision, especially when working with multiple active ingredients and sensitive propellant- based delivery systems. While carrying out routine batch-release testing for a complex inhalation product, Eurofins BPT Finland encountered a recurring and technically challenging assay issue in the combination inhaler's analytics.

The project involved complex testing, e.g. NGI (APSD), Delivered Dose, related substances for APIs, and assay. While most analyses consistently met specifications, the assay occasionally produced Out- Of- Specification results. These deviations appeared sporadically: some replicates passed; others failed, and entire batches alternated between successful and unsuccessful outcomes. Nothing suggested an actual quality defect in the product, yet the uncertainty risked substantial delays in global supply.

To investigate thoroughly, teams across laboratories and Quality Assurance collaborated closely with the client's global development and manufacturing sites. Joint troubleshooting sessions, reciprocal site visits, and even video-recordings ensured full transparency throughout the process.

A detailed GAP analysis across three international laboratories revealed that even tiny procedural and environmental variations could influence crystallisation behaviour and extraction efficiency. With the aerosol formulation, propellant behaviour during sample preparation proved especially sensitive. Subtle differences in evaporation, humidity, and extraction handling between laboratories were potential contributors.

The root cause was identified to be a combination of several factors, and the findings enabled a robust update of the analytical method, adding clearer requirements for environmental conditions and harmonising all practical steps across laboratories. The case also highlighted the limitations of the original indirect method transfer approach. Going forward, a direct method transfer will be implemented, with both laboratories analysing samples in parallel to verify full reproducibility.

Today, the method performs reliably, and the client's batches proceed without delay. This case shows how inhalation expertise, strong collaboration, and systematic problem-solving make Eurofins BPT Finland a trusted partner for complex analytical work. As a service laboratory, Eurofins BPT Finland consistently goes the extra mile, and the client expressed sincere appreciation for the support provided by the top specialists.

THE CRUCIAL ROLE OF HIGH-FIDELITY SPENT MEDIA ANALYTICS IN AI-DRIVEN BIOPHARMACEUTICAL R&D AND PRODUCTION

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As the biopharmaceutical industry enters the BioPharma 4.0 era, driven by the integration of Artificial Intelligence (AI) and Machine Learning (ML), the foundation of successful AI integration lies in the quality of the data used to train and validate predictive models. Eurofins Spinnovation Analytical B.V. stands at the forefront of this evolution by providing high-quality Spent Media Analysis (SMA) through its propri-etary SPEDIA™ platform, an analytical service designed to deliver precise, reproducible metabolic insights essential for AI-driven bioprocess optimisation.

Our SPEDIA™ platform combines three advanced analytical technologies: Nuclear Magnetic Resonance Spectroscopy (NMR), Liquid Chromatography-Mass Spectrometry (LC-MS) and Inductively Coupled Plasma-Optical Emission Spectrosco-py (ICP-OES). This unique combination ensures high precision in quantitative metabolite profiling, covering a broad range of culture media components, including amino acids, sugars, organic acids, vitamins, polyamines, buffers, surfactants, and trace elements. The result is a comprehensive, structured, and quantitative dataset that empowers clients to develop robust AI models for cell culture prediction, real-time process control, and automated quality assurance.

The importance of high-quality analytical data for AI and regulatory compliance

AI applications in biopharmaceutical production demand data that is accurate, reproducible, and compliant with regulatory standards. Eurofins Spinnovation Analytical's SMA service delivers:

- **Enhanced Predictive Accuracy:** AI models (like digital twins) trained on high-fidelity data yield more reliable insights into cell growth and metabolite consumption.

- **Improved Process Control:** Better process understanding through SMA, and digital twins help prevent deviations before they impact production.
- **Batch-to-Batch Consistency:** Reliable quality control of raw material composition detects and reduces variability, improv-ing reproducibility.
- **Regulatory Confidence:** Structured, validated data simplifies compliance with global GMP standards.
- **Cost Efficiency:** Better process understanding leads to re-duced production costs and increased yields.

Eurofins Spinnovation Analytical's commitment to data integrity and standardisation also addresses key challenges in AI-enabled biopharma, including scalability, data security, and platform compatibility. By providing high-fidelity SMA data, Eurofins Spinnovation Analytical enables clients to develop AI models that optimise bioprocesses in real time, predict cell culture dynamics, ensure batch consistency, and automate quality control for enhanced efficiency and reliabili-ty in biopharmaceutical production.

As AI continues to reshape biopharmaceutical R&D and production, the need for reliable, high-quality SMA data has never been more prominent. Eurofins Spinnovation Analytical's SMA service empowers biopharma, biotech, and CDMO companies to fully leverage AI in their development process-es. The SPEDIA™ platform provides clients with essential met-abolic insights that accelerate decision-making, streamline development, and enhance production efficiency.

For more information, visit: www.eurofins.nl/en/biopharma-product-testing-nl/services/facility-and-process-control/spent-media-analysis/ or contact us at: info.EBPT-NL@bpt.eurofinseu.com

A UNIQUE INTEGRATED OFFER SUPPORTING BIOLOGICS DEVELOPMENT WITHIN EUROFINS

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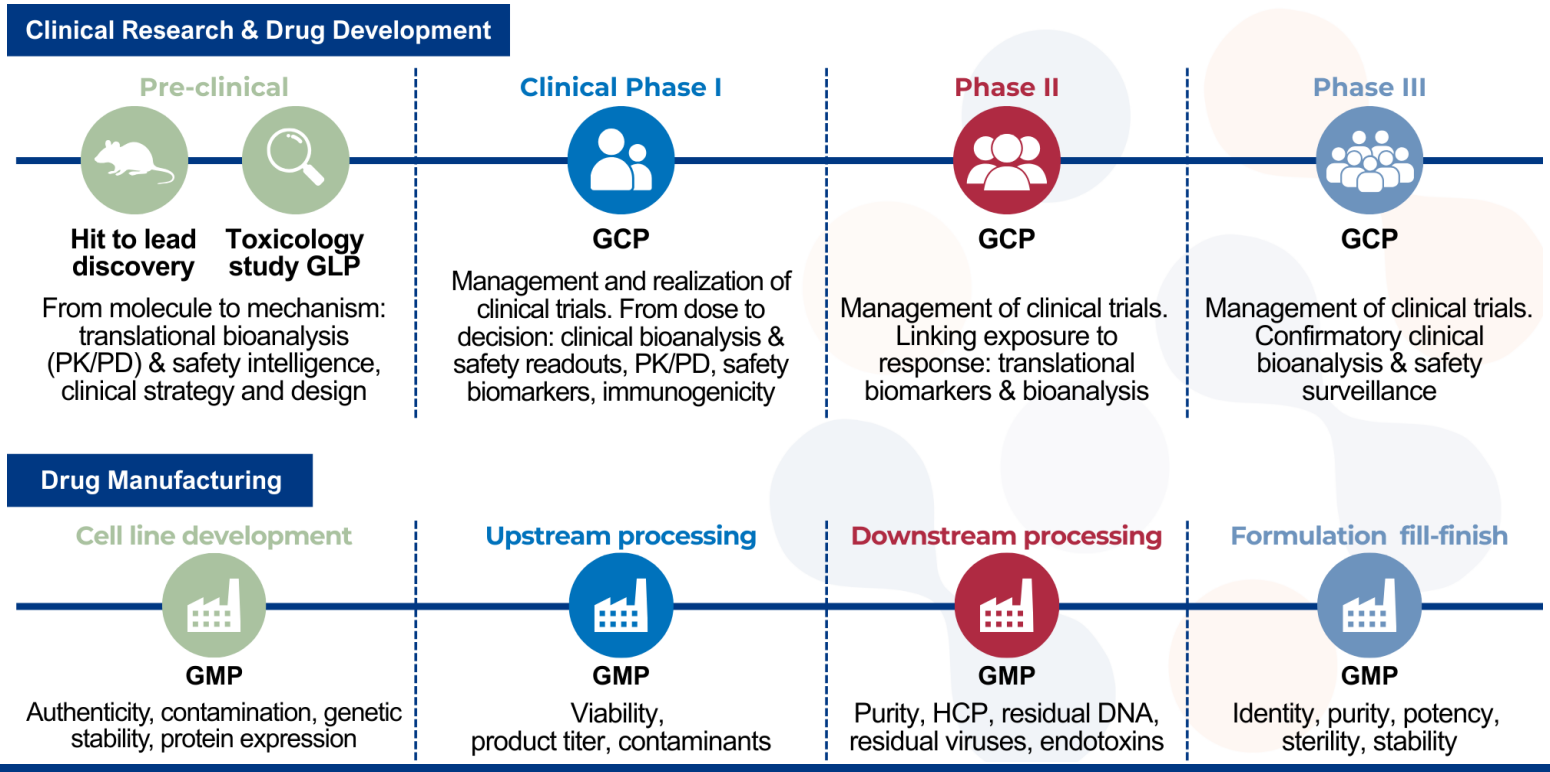
Eurofins offers a unique and fully integrated solution to support the development of biologics, including therapeutic antibodies such as ADCs, bispecific antibodies, recombinant proteins, conjugates, and emerging biotherapeutic formats. Because these complex molecules require advanced characterisation, robust bioanalysis, and strict GMP control throughout development and manufacturing, Eurofins combines the strengths of three complementary expert entities: Eurofins Optimed, Eurofins ADME Bioanalyses, and Eurofins BPT Biologics. Together, they provide a seamless technical continuum from preclinical GLP studies through early and late phase clinical development, while ensuring consistent, safe, and high-quality production of biologic drug batches.

Eurofins Optimed brings over 35 years of clinical trial expertise, with a state-of-the-art Phase I unit and a network of sites in Europe and the US. Their teams support sponsors across the full translational pathway—from protocol design to dose selection and escalation strategies. They are particularly experienced in first-in-human biologics, managing cold-chain requirements, specialised pharmacy preparation, and 24/7 medical oversight. Eurofins ADME Bioanalyses offers industry-leading expertise in bioanalytical method development, therapeutic antibody quantification, pharmacokinetics, immunogenicity, and biomarker analysis. Using advanced platforms (ELISA, ECL, cell-based assays, LC-MS/MS, immunopurification, antibody characterisation), they provide highly sensitive, reliable data aligned with FDA, EMA, and ICH guidelines to support confident decision-making.

Eurofins BPT Biologics completes the service offering with comprehensive QC expertise for biomolecule manufacturing—from process development and optimisation to GMP or preclinical/clinical stage production. Continuous quality controls ensure batch reliability, reproducibility, and regulatory compliance, providing developers with well-characterised materials ready for analytical and regulatory evaluation.

By integrating manufacturing, bioanalysis, preclinical, and clinical capabilities, Eurofins minimises logistical risks, accelerates study initiation, improves scientific consistency, and simplifies project management through a single point of contact. This cohesive, agile model provides a strategic advantage for biopharmaceutical companies seeking to efficiently and securely advance their biologic programmes towards success.



SUPPORTING CLIENTS THROUGH COMPLEX BIOPHARMA CHALLENGES

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Dungarvan, Ireland - Biopharma developers today face increasing pressure to accelerate development timelines, ensure product quality, and meet stringent global regulatory expectations. From early analytical characterisation to late stage device compatibility, each step introduces scientific and operational challenges that can impact product integrity and patient safety.

The Biopharmaceutical Department at Eurofins Biopharma Product Testing (EBPT) in Dungarvan is built to help clients overcome these hurdles with confidence. Our laboratory brings together deep scientific expertise, advanced analytical platforms, and a strong understanding of regulatory requirements to support every stage of the product lifecycle. Whether clients need robust method development, reliable validation, stability insights, or device performance assessments, our teams deliver data driven solutions that enable informed decision making and regulatory success.

Precision Meets Innovation

Biopharma innovators often struggle with the complexity of modern molecules, the need for orthogonal analytical approaches, and the demand for rapid, high quality data. EBPT addresses these challenges through a comprehensive suite of technologies designed to characterise products with precision and scientific rigor. Our capabilities include:

Chromatography Excellence
HPLC and UHPLC systems, complemented by a wide array of HPLC instruments, enable precise separation and quantification of complex molecules

Protein Characterisation
Maurice Instrument facilitates rapid analysis of monoclonal antibodies, viral particles, and ADCs using CE-SDS and icIEF methods

Protein Purity Assessment
Automated Capillary electrophoresis instrumentation for understanding purity, integrity and charge.

Particle Testing
Tools like the Mastersizer, Zetasizer and HIAC particle counter to provide critical insights into product stability along with MFI Imaging as an orthogonal tool.

Spectroscopy & Plate-Based Assays
Solo VPE, Shimadzu for protein analytics, and SpectraMax plate readers support sensitive detection and quantification.

Specialised Testing
Karl Fischer Coulometry, Turbidity, Colorimetry and Osmolaity for solution properties round out the lab's capabilities

Global Standards, Local Expertise

Biopharma companies must navigate evolving EMA, FDA and ICH expectations while maintaining operational efficiency. EBPT supports this by combining global regulatory alignment with the agility of a local, collaborative team.

We partner with the clients to shape study designs that align with regulatory expectations, minimise development risks, and keep programmes moving efficiently. Drawing on extensive experience across biologics, biosimilars, vaccines, and advanced therapies, we equip clients with the assurance and clarity needed to advance their products confidently from development through to market.

Safeguarding Device Integrity

Drug device combination products introduce additional layers of complexity from mechanical robustness to sterility assurance. Clients rely on EBPT to ensure their delivery systems perform safely and consistently.
Our device testing capabilities include:

- Mechanical testing with Zwick and Instron instruments.
- CO_2 based container closure integrity (CCI) testing to verify sterility.
- GMP compliant aseptic analysis within biological safety cabinets.

What's Next?

As client needs evolve, EBPT continues to expand its scientific capabilities. Upcoming features will highlight advanced technologies such as:

- SEC MALS for precise molecular weight and aggregation analysis
- Enhanced Instron based device performance testing
- Expanded CO_2 based CCI methodologies

With a strong infrastructure and a commitment to scientific excellence, EBPT remains a trusted partner for biopharma companies striving to transform scientific innovation into safe, effective medicines for patients worldwide.

EUROFINS' GLP 1 AGONIST MULTIPLEX TESTING ENABLES RAPID, DATA-DRIVEN DECISION-MAKING AND IMPROVES SUCCESS RATES IN TREATING COMPLEX DISEASES

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With the rapid expansion of GLP 1 receptor agonists in the treatment of obesity, type 2 diabetes, and metabolic disorders, the demand for highsensitivity, high-throughput bioanalytical platforms has never been greater. At Eurofins BioPharma Product Testing (BPT) Ireland, we have invested in the MESO QuickPlex® SQ 120MM, a state of the art electrochemiluminescence (ECL) detection system, to deliver fast, precise, and regulatory compliant testing for our global client base.

Why the MESO QuickPlex® SQ 120MM?

The MESO QuickPlex platform offers unmatched analytical performance for ligand binding assays and immunogenicity testing, making it ideal for the potency, pharmacokinetic (PK), and biomarker analysis of GLP 1 agonists. Its unique ECL technology provides:

- Ultra low detection limits with low sample volume
- Multiplexing capability with low turnaround time
- Exceptional reproducibility
- Wide dynamic range

Applications in GLP 1 agonist development

Our Irish team leverages the MESO QuickPlex SQ120MM for:

- Potency assays aligned with GLP 1 receptor pharmacology
- Simultaneous quantitation of multiple analytes within a single well, using U-Plex and V-Plex multiplexing platforms

This capability supports the development of multi-target therapies by enabling rapid, data-driven decision-making across both preclinical and clinical stages. It facilitates efficient candidate selection, dosing optimisation, and enhances translational predictability. Additionally, it contributes to mechanism-of-action research and adaptive trial design, ultimately improving development efficiency and success rates in treating complex diseases such as metabolic disorders.

Multiplexing strategy using U-PLEX and V-PLEX platforms

Multiplexing is a powerful analytical technique that enables the simultaneous quantitation of multiple analytes within a single well. This approach significantly enhances efficiency by reducing the number of plates required for analysis and conserving valuable sample volume, allowing up to 10 different analytes to be measured from just 20 µL of sample. At the Eurofins BPT's Ireland site, we are adopting U-PLEX multiplexing technology to customise assay plates and optimise experimental conditions tailored to our specific analytical needs. Following this, we can validate to V-plex level, resulting in a validated kit-based assay that offers enhanced robustness and reproducibility for routine testing. This strategic approach is expected to streamline our workflows, improve data quality, and support high-throughput analysis in a cost-effective manner.

Partnering for Success

Whether you are advancing a first in human GLP 1 analogue or optimising a late stage clinical candidate, the MESO Quick-Plex SQ 120MM at Eurofins BPT Ireland offers the precision, speed, and compliance to accelerate client programs.

Contact us at: EurofinsBPT-IE@bpt.eurofinseu.com or visit our website here: www.eurofins.ie/biopharma-product-testing-ireland/

Comprehensive GMP Testing Services

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