BIOPHARMA - MEDICAL DEVICES - BIOCIDES

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Advancing AAV therapies to regulatory approval - Eurofins BPT supports methods for EU release

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The genetic medicine landscape continues to accelerate, with rapid advances across modalities, including lentiviral *ex vivo* therapies, CRISPR-based gene editing, and RNA/oligonucleotide technologies. Among these, *in vivo* AAV (Adeno-Associated Virus) gene replacement therapies represent the largest portion of late-stage clinical pipelines and the majority of gene therapies progressing toward regulatory approval. AAV vectors deliver a functional gene directly to patient cells using a replication-incompetent viral system – an approach that introduces unique analytical challenges due to biological complexity, lot-to-lot variability, and inherently small batch sizes.

Since 2017, approximately 10 AAV therapies have received FDA approval, with seven also approved by the EMA. While both agencies maintain rigorous review standards, their approaches to QC release requirements differ. The FDA typically applies a flexible, risk-based philosophy, whereas the EMA requires a more prescriptive, fully developed analytical package prior to commercialisation. In the EU, AAV gene therapies fall under the category of Advanced Therapy Medicinal Products (ATMPs) and, importantly, are not covered by any Mutual Recognition Agreements. As mandated by EU Directive 2001/83/EC, Article 51(1)(b), ATMPs must undergo in-country testing within an EU member state before market release.

Critical Quality Attribute (CQA)	Characteristic	Analytical Method[1]
Identity	Confirm correct vector genome sequence	Sanger Sequencing
		Next Generation Sequencing (NGS)[2]
	Confirm correct capsid	Mass Spectrometry
		Capsid ELISA
		Western blot (automated and manual)
	Confirm Genetic Payload	qPCR
		ddPCR
Purity	Quantification of process Impurities	Host cell DNA by ddPCR
		Host cell protein by ELISA
		Residuals by HPLC
		Residuals by LCMS
		Residuals by ELISA
	Quantification of Product Related Impurities	% Empty vs Full Capsid by AUC
		% Empty vs Full Capsid by SEC-MALS
		Aggregates by DLS
		Aggregates by SEC-MALS
		Replication Competent AAV
		Purity by CE-SDS
Potency	Cell based assay to demonstrate biological activity related to the mechanism of action	Western blot (automated and manual)
		ELISA
		Cell based reported Assay
	Cell based assay to demonstrate transgene expression	TCID50 Infectivity Assay
Quantity	Determination of Strength or Dose	ddPCR
		qPCR
Safety	Sterility	Ph. Eur. 2.6.1
	Endotoxin	Ph. Eur. 2.6.14
	Mycoplasma	Mycoplasma qPCR[2]
	Advantage Agents	Cell based Replication Competent Testing
Stability	Visual Inspection	Ph. Eur. 2.9.20
	Colour	Ph. Eur. 2.2.2
	Clarity	Ph. Eur. 2.2.1
	pH	Ph. Eur. 2.2.3
	Osmolality	Ph. Eur. 2.2.35

[1] *Methods listed below are not fully comprehensive of EBPT Ireland's AAV Gene Therapy capabilities but give an overview of critical methods requested by the EMA. If information on additional methods are required please don't hesitate to reach out to EurofinsBPT-IE@bpt.eurofinseu.com.*

[2] *Note these methods are not currently offered at our Ireland site but are offered at other sites in our European network where testing for EU release can be wholly managed and coordinated by EBPT.*

To meet EMA expectations, manufacturers must apply orthogonal analytical strategies for each Critical Quality Attribute (CQA), including identity, potency, purity, quantity, safety, and stability. The accompanying table outlines these CQAs and the gold-standard analytical methods typically required.

At Eurofins BPT Ireland, we are exceptionally well positioned to support clients preparing AAV therapies for the European market, with extensive experience in the commercial release of AAV programmes and in generating data packages for regulatory filings. As shown in the accompanying table, our laboratory delivers the complete suite of QC methods required for both AAV drug substance and drug product, supported by deep technical expertise in method development, validation, transfer, and comparability assessments essential for EMA submissions. Leveraging our strong track record in producing robust regulatory-ready datasets, we help de-risk submissions and accelerate programme progression right through to commercial release.

Significant recent investment has further strengthened our gene therapy offering, including the expansion of our Biosafety Level 2 facilities and the addition of a purpose-built laboratory dedicated to AAV potency testing. We are also proud to be the first contract testing laboratory in Europe to offer GMP AUC, underscoring our leadership in advanced AAV characterisation and our commitment to expanding industry leading and life-enhancing capabilities.

With cutting-edge capabilities, regulatory expertise, and a proven record in supporting commercial release for global gene therapy programs, Eurofins BPT Ireland stands ready to help bring the next generation of transformative AAV therapies to patients across Europe.

For more information contact us at: *EurofinsBPT-IE@bpt.eurofinseu.com* or visit: *www.eurofins.com/biopharma-services/product-testing/locations/ireland/.*

Viral safety 2.0 – the power of next-generation sequencing

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Traditional viral safety testing has long relied on *in vivo* and *in vitro* adventitious agent tests – methods that, while foundational, are limited by their narrow scope and lengthy turnaround times. As biopharmaceutical complexities increase, the industry has been transitioning toward viral safety, driven by the transformative power of Next-Generation Sequencing (NGS).

The challenge: risk and uncertainty

For clients, the limitations of legacy testing manifest as significant risks. Patients face the potential threat of "dark matter" viruses: emerging or cryptic contaminants that traditional assays fail to detect due to lack of specific primers or narrow host-cell susceptibility. For the client, these gaps translate into regulatory uncertainty and operational bottlenecks. A contamination event detected late in the manufacturing cycle can lead to catastrophic facility shutdowns, supply chain disruptions, and most importantly, compromised patient safety. Furthermore, the 28-day duration of traditional cell-based assays delays the delivery of life-saving therapies, particularly in the fast-paced field of Advanced Therapy Medicinal Products (ATMPs).

The solution: a client-centric NGS strategy

As a service provider, making NGS "client-centric" means evolving beyond mere data generation to provide actionable intelligence. By leveraging Metagenomic NGS (mNGS), Eurofins BPT offers a "catch-all" diagnostic tool that identifies known and unknown sequences simultaneously. To address client pain points, our approach focuses on:

- **Accelerated timelines:** reducing testing cycles from weeks to days, allowing for faster batch release.
- **Bioinformatic clarity:** translating complex genomic data into simplified, risk-based reports that ease the burden of regulatory filings.
- **Mitigation of false positives:** implementing robust bioinformatic pipelines to distinguish between environmental noise and genuine biological threats.

Ultimately, NGS is not just a technological upgrade; it is a commitment to a higher standard of care. By integrating NGS, Eurofins BPT provides clients with a proactive safety net, ensuring that the path from bench to bedside is swifter, more transparent, and uncompromisingly secure.

For more information, visit: Next-Generation Sequencing (NGS) - Eurofins Denmark

Eurofins PSS and BPT deliver integrated EM/UM support across all phases

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Whether qualifying a new facility, running routine utility and environmental monitoring, or scaling production, the real challenge is making every step operate as one: without gaps, delays, or compliance risks.

With an agile dual-model, integrating Professional Scientific Services® (PSS) and BioPharma Product Testing (BPT), Eurofins delivers a streamlined, end-to-end approach that aligns sampling, logistics, testing, and data management within one coherent system built for stability and GMP excellence.

Your challenges – clearly understood

Clients consistently face similar pain points:

- **Separate teams for sampling, logistics, and testing** cause handover inefficiencies.
- **Scaling monitoring for new lines**, investigations, or increased capacity strains internal resources.
- **Using temporary workers** from different vendors without a dedicated onsite leader results in unstable operations, high staff turnover, ongoing retraining burden, inconsistent performance, and overall higher costs.
- **Manual ordering and reporting** increase data integrity risks.
- **Qualification outputs often fail** to seamlessly transition into routine EM/UM operations.

Our solution – one integrated Eurofins PSS & BPT ecosystem

Eurofins' network of laboratories connects qualification, monitoring, logistics, testing, and data management into a unified, audit-ready workflow. From facility start-up to daily EM/UM execution, we ensure processes, responsibilities, and documentation remain aligned and fully traceable, creating a robust monitoring programme from day one.

- **Our onsite PSS team managed by a dedicated PSS Group Leader,** who manages daily workload, ensures sampling accuracy, coordinates with BPT labs, and serves as a single point of contact.
- **Our stable PSS workforce brings reduced turnover,** supported by HR best practices, employee-centric culture, structured onboarding, and continuous training.
- **Routine EM/UM execution is aligned with the client's validated monitoring plan,** including defined locations, frequencies, limits, and qualification-based control strategies.
- **Sampling, logistics, testing, and reporting are integrated into one workflow,** reducing handovers, turnaround time, and compliance risk.
- **Predictable logistics flow includes onsite pick-up,** validated transport boxes, chain-of-custody, and time-bound daily windows for sampling, transfer, and test initiation.
- **LabAccess.com® enables digital transparency** for online ordering, real-time status tracking of samples, results access, historical data trending and OOS history.
- **Automated LIMS-to-LIMS data transfer** offers secure delivery of results directly into your systems, eliminating manual transcription errors and strengthening ALCOA+ data integrity.

- **Continuous improvement enforced through LEAN,** including standard work, visual management, PDCA problem solving, and waste-reduction initiatives across the entire EM/UM workflow.

Discover the scientific solutions our clients trust and value, and find out how we can solve your challenges cost-effectively and proficiently. For more information, visit: www.eurofinspss.com and www.eurofins.com/biopharma-services/product-testing/process-validation/facility-monitoring-and-support/

How will ISO 10993-1:2025 affect the future of preclinical medical device compliance?

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The publication of ISO 10993-1:2025 marks a major turning point in the way manufacturers approach the biological safety of medical devices. Far from being a simple revision, the new edition reshapes the evaluation process into a fully integrated, risk-based, and lifecycle-oriented framework aligned with ISO 14971. For companies operating in an increasingly complex regulatory environment, the standard sets clearer expectations and offers opportunities to improve efficiency, reduce unnecessary testing, and strengthen compliance.

The Biological Evaluation Plan (BEP) is now a mandatory and central element of the evaluation process. The BEP anchors together device description, intended use, hazard identification, acceptability criteria, and testing strategy. Furthermore, the introduction of reasonably foreseeable misuse forces the biological risk assessor to consider systematic human use within the factors of impact on biocompatibility.

The new edition also embraces a lifecycle perspective, requiring manufacturers to continuously reassess biological risks from early design stages through post-market activities. Material changes, degradation, reprocessing, and post-market feedback now play an integral role in maintaining biological safety.

Another critical innovation is the introduction of biological equivalence, allowing companies to justify the safety of a device through comparison with established reference products. Combined with enhanced chemical characterisation requirements and toxicological risk assessment, this approach can significantly reduce unnecessary animal or clinical testing, provided the equivalence is robustly documented.

The revision also modernises exposure categorisation by focusing on contact days, intermittent exposure, and bioaccumulation potential. This ensures a more realistic – and sometimes more conservative – assessment of long-term risks, especially for devices used repeatedly over short intervals.

Finally, the standard reinforces the use of New Approach Methodologies (NAMs), *in vitro* systems and *in silico* tools that support the global trend toward reducing animal testing while improving human relevance.

While the regulatory landscape continues to evolve, many manufacturers are discovering that navigating biological risk assessment under ISO 10993 1:2025 requires not only technical expertise but also a strategic, well structured approach.

Eurofins Medical Device Services is equipped to support you across the entire process – from defining a robust Biological Evaluation Plan to guiding equivalence strategies, analysing chemical and toxicological data, and integrating post market evidence into a compliant lifecycle evaluation. With multidisciplinary expertise spanning toxicology, regulatory affairs, and device development, we help transform complex requirements into clear, actionable pathways. Partnering with us means accelerating your route to conformity, while ensuring the highest standards of patient safety and regulatory confidence.

For more information, visit: www.eurofins.com/medical-device.com or contact us at: medical-device@mds.eurofinseu.com

Eurofins generates unique integrated capabilities offer to support clients' biologics advancements

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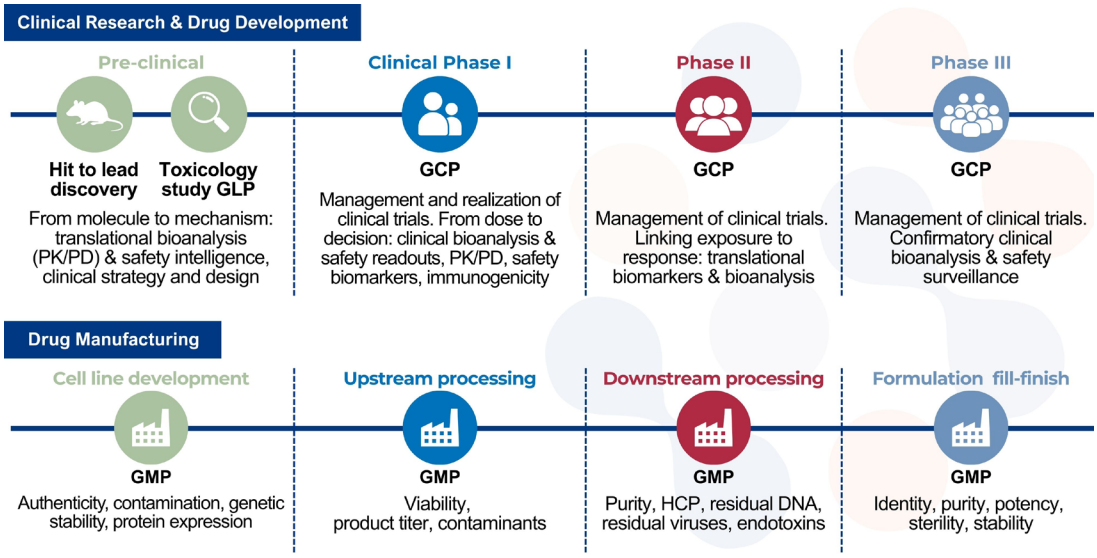
The development of biologics, including therapeutic antibodies such as Antibody Drug Conjugates (ADC), bispecific antibodies, recombinant proteins, conjugates, and emerging biotherapeutic platforms, requires end-to-end expertise covering advanced bioanalytical characterisation and high-quality bioanalysis during drug development, as well as GMP controls during the manufacturing process. To meet rising expectations for speed, scientific precision, and seamless coordination across R&D programmes, Eurofins offers an integrated solution built on the combined strengths of three complementary entities: Eurofins Optimed, a clinical centre and CRO; Eurofins ADME Bioanalyses, a leading expert in bioanalysis, pharmacokinetics, and immunogenicity; and Eurofins BPT Biologics, specialised in GMP testing in biologics manufacturing. Together, they create a unique technical continuum that supports biotech and pharmaceutical developers from preclinical GLP and early clinical trials, to late phase clinical GCLP stages. In parallel, they deliver controlled, reproducible production to help clients ensure their biologic drug is safe, pure, potent, and consistently produced.



At Eurofins Optimed, clients benefit from more than 35 years of experience in managing clinical trials, with a state-of-the art Phase I unit, or via a network of clinical sites across Europe and America. Their expertise guides you from protocol design through the full translational pathway, from preclinical to clinical trials: supporting go/no go decisions, starting-dose selection, tailored dose-escalation strategies based on PK profiles, and the choice of endpoints and target population. The Eurofins team has the clinical expertise to manage clients' biologics, particularly for their first administration in humans (FIM), while considering their specific characteristics and requirements, such as compliance with the cold chain, specific pharmacy preparations, and administrations. Understanding specific medical constraints and risks, its medical team is trained and available 24 hours a day, 7 days a week.

Eurofins ADME Bioanalyses delivers industry leading expertise in the development and validation of bioanalytical methods, therapeutic antibody quantification, pharmacokinetic and immunogenicity assessments, and biomarker analysis.

Harnessing state-of-the-art platforms, including immunoassays (ELISA, ECL, cell-based assays), LC MS/MS, and advanced analytical technologies such as immunopurification and antibody characterisation, our teams generate highly sensitive, reliable, and fully regulatory aligned data. Compliant with FDA, EMA, and ICH guidelines, we ensure that every dataset empowers confident, timely decision making across all stages of drug development.

To complete the service offer, Eurofins BPT Biologics brings full expertise of multidisciplinary Quality Control (QC) in the manufacturing of biomolecules, from process development and optimisation to GMP compliant or preclinical/clinical stage adapted production. Continuous quality controls throughout manufacturing ensure batch reliability, reproducibility, and regulatory alignment. This strong industrial capability provides developers with well characterised materials ready for subsequent analytical and regulatory evaluation.

The integration of manufacturing, preclinical, and clinical expertise, including bioanalysis conducted within the Eurofins network of laboratories, generates substantial added value for biologics developers. Firstly, the end-to-end continuity between production and analyses minimises logistical risks, avoids additional delays, and reduces variability between batches. Early collaboration between manufacturing and analytical teams enables optimised method development, faster study initiation, and greater scientific consistency throughout the programme. Clients also benefit from streamlined project management through a single point of contact, offering greater visibility, simplified coordination, and improved responsiveness.

By combining the industrial strength of Eurofins Optimed, Eurofins ADME Bioanalyses, and Eurofins BPT Biologics, Eurofins delivers comprehensive, agile, and strategic solutions designed to secure and accelerate biologics development. This integrated approach responds to the increasingly complex demands of today's biopharmaceutical landscape and represents a significant advantage for organisations seeking reliable, high performance partners to guide their biotherapeutic programmes toward success.For more information, visit: www.eurofins-optimed.fr/; www.eurofins.com/biopharma-services/adme/; and www.eurofins.fr/biopharma-product-testing/

Strategy Beyond the Bench: Eurofins launches new U.S. consulting chapter in MedTech strategy & policy

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Eurofins is pleased to launch Eurofins Medical Device Consulting – the latest investment in supporting critical innovation across MedTech in the U.S.

In launching this key offering, Eurofins Medical Device Consulting marks an inflection point for its Medical Device, Combination Product, and Diagnostic service portfolio – moving from testing services provider to full-lifecycle partner in strategy and insights. Building upon world-class bioanalytical expertise, Eurofins Medical Device Consulting delivers strategy beyond the bench.

Eurofins Medical Device Consulting launches with a focus on regulatory policy and strategy. Centered in Washington, DC, and connected across the globe – engagement is always local. Our consultant team brings cross-functional experience, leveraging background in regulatory strategy, product development, and government relations to support your product from conceptualisation through FDA authorisation and beyond.

From investment diligence, commercial strategy, regulatory, quality, and toxicology consulting to human factors engineering, Eurofins' approach drives scientific solutions, client trust and satisfaction, and patient safety.

Key Takeaways:

- Eurofins Medical Device Consulting broadens its impact on client engagement and innovative solutions – turning quality data into actionable strategy and insight.
- Eurofins Medical Device Consulting's most recent investment in meeting the demands of MedTech transcends expertise to support every phase in the product lifecycle.
- Eurofins Medical Device Consulting supports the stakeholder spectrum - from venture capital diligence to premarket submission strategy, and post-market compliance.

For more information, visit: www.eurofins.com/medical-device/consulting/

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