

BioPharma Services
News

BIO/PHARMA - MEDICAL DEVICES - COSMETICS - BIOCIDES

Helping the development of cell and gene therapies to enhance disease treatment

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The development of Advanced Therapy Medicinal Products (ATMPs), such as gene and cell therapy products, has made significant progress in the treatment of many diseases, including cancer, genetic, and autoimmune disorders. Regulatory agencies have seen a large increase in the number of submissions over the last two years, and further increases are expected to continue for years to come. With the promise to enhance treatment, greatly reduce side effects, and potentially cure many types of diseases and disorders, these therapies are in high demand, and biopharma companies are in a race to the clinic. However, these technologies are very complex in nature and are vastly different from traditional biopharmaceutical products, especially when it comes to the use of these products for personalised medicine. The complexities span the development pipeline, creating challenges for manufacturing, testing requirements, regulatory approval, and commercialisation.

In gene therapies, a defective gene is replaced with a functional one using a transmission system called a vector. This may occur by injecting the vector into the patient, or cells may be removed from the patient, exposed to the vector, and then returned to the patient. In some cases a single therapy may be used for many patients with the same condition. In other cases, there may be a custom treatment for each patient (known as personalised medicine). Gene therapies provide the ability to treat genetic diseases such as hemophilia by a single gene therapy treatment, in contrast to repeated treatments needed with conventional therapies. In addition to enhanced treatments, other potential benefits include reduced side effects, and the potential to cure, rather than just treat, many types of diseases and disorders.

With cell therapies, human or animal cells are administered to “repair, replace, regenerate, or augment a recipient’s cells, tissue, or organs that are diseased, dysfunctional, or injured” (US Pharmacopeia <1046>). The cells may be used without alteration, or they may be engineered to add a specific function (e.g., using CRISPR or CAR-T technologies). Cell therapies may be used for disorders such as knee cartilage defects or organ failure, where cells can be implanted to the damaged tissue.

Eurofins BioPharma Product Testing supports the development of ATMPs both for traditional use as well as for use in personalised medicine. Eurofins provides comprehensive GMP-compliant testing support to ensure the identity, potency, purity, and safety of starting materials, cell and virus banks, intermediate products, vectors, and final drug products, as well as support for manufacturing process development and validation. For more information visit: *www.Eurofins.com/bpt*

Early stage formulation strategy for a smooth drug product lifecycle

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The drug product life cycle for oral dosage forms generally covers two major phases–early stage or phase appropriate formulation development and late stage commercialisation activities. At the early stage, formulation and drug product strategies tend to focus on speed to clinic and "drugability" (i.e. solubility enhancement and improvement of drug exposure at the site of action). At the late stage, efforts shift to process and manufacturability, with an eye on commercialisation. Oftentimes a programme's success or advancement to late stage is driven by early clinical data to reach the next corporate milestone.

A phase appropriate formulation development programme must consider all aspects of the drug product life cycle as well as the physicochemical characteristics of the compound. The knowledge gained at the early stage helps favour the formulation and process strategies which target increased drug solubility and exposure at the site of action.

Eurofins CDMO has a formulation team focused on the challenges of early stage development, thus paving the way for a successful late stage programme. To address drug solubility and absorption, strategies such as amorphous solid dispersions, self-microemulsifying drug delivery systems, lipid-based systems, API complexation and API micronisation are often targeted. The formulation team works synergistically with the pre-formulation and solid state characterisation teams to develop phase-appropriate and advanceable formulations.

The formulation team is also highly skilled at addressing the challenges of the late stage drug product lifecycle, normally associated with manufacturability improvement and performance. The knowledge acquired from the early phases can be used to execute bridging studies that aim to further optimise the formulation in the later stages of drug development.

Eurofins CDMO provides phase appropriate solutions for all aspects of the drug product lifecycle from pre-clinical through to commercialisation. For more information visit: *www.eurofins.com/biopharma-services/cdmo/*

Viracor Eurofins' new state-of-the-art cryo storage enhances sample security and storage capabilities

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Cryogenics has proven to be especially useful in the pharmaceutical industry, where cryogenic storage is being utilised to ensure the efficacy of advanced therapeutics, such as biologics and stem cell therapies. Given these samples are irreplaceable in many instances, Viracor Eurofins' pharma and biotech client partners rely on this expertise for their clinical trial sample management, including sample storage that preserves viability and functionality of cells. With the recent installation of Viracor Eurofins' Brooks BioStore™ III Cryo -190°C storage system, clients are afforded an enhanced level of safety, integrity, and 21-CFR-11 regulatory compliance that is essential to meeting both current and future needs. Long-term controlled temperature storage systems, like the Biostore III, are an increasingly essential part of a comprehensive clinical trial and research materials management and storage solution that ensures maximum security and complete chain of custody.

This new automated liquid nitrogen (LN2) cryogenic storage system provides superior protection, accessibility, and record-keeping for cells and other sample assets at -190°C. Specifically, it is currently the only cryogenic storage solution that combines the protection, safety, and accessibility of a manual high-efficiency LN2 freezer, with advanced automation features such as vial-level inventory control, barcode reading automation, and sample transportation. It also offers the ability to be integrated with Viracor Eurofins' LIMS system, on-demand and 21-CFR-11 level report generation, and sample integrity calculator that protects samples from excessive warming by predicting their temperatures based on experimental evidence.

The design of the system also allows Viracor Eurofins' to use it as a shared resource, for both BioPharma and Clinical Diagnostics needs, due to the administrator-defined library system and access control elements. Lastly, the emergency situation protection on the BioStore III provides greater than 20 days of temperature stability in the case of energy or LN2 loss, giving clients added peace of mind. For more information, visit: *www.viracor-eurofins.com/biopharma-services/*

Validating drinking water disinfection procedures according to EU BPR regulation with Eurofins/UBA lab-scale solution

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Disinfection procedures are of widely recognised relevance in ensuring the supply of safe drinking water. Disinfection is usually the final step during the production of drinking water, acting as an essential barrier against widespread human pathogens. Active substances for the disinfection of drinking water should be effective against a wide range of bacteria and viruses.

Authorisation of disinfectants for drinking water treatment in the EU is under the scope of the Biocidal Product Regulation (BPR), and the product authorisation requires demonstration of the treatment efficacy under conditions as described by the European Chemicals Agency (ECHA) disinfection efficacy guidance, Product type 5 (PT5) section (2018).

Until now, the only test method officially accepted by ECHA in the BPR disinfection efficacy guidance is the one established by the German Environment Agency (UBA), Section Drinking Water Treatment, the UBA test (2013). The protocol is part of BPR product authorisation for the following water treatment claims:

1. Disinfection at the drinking water suppliers and their water distribution systems

2. Disinfection of raw water for individual supply

3. Disinfection of water for animals

Eurofins BioPharma Product Testing developed an in-house test system made of a test rig working in a flow-through mode similar to the disinfection procedures in waterworks, but under tightly defined conditions for input water DOC (Dissolved Organic Carbon), pH, temperature, and flow-rate – exactly according to the requirements established by the UBA test (see photo).

Additionally, dosage systems for disinfectants, bacteria and viruses, and sampling points of microbiological and chemical analysis have also been validated by performing simulated use tests with the two standard disinfectants, as required by the German test guideline. In this way, Eurofins BioPharma Product Testing is currently the only CRO that can perform the UBA test and meet all BPR ECHA guidance requirements for biocides to be used for the treatment of drinking water. For more information, visit: *www.eurofins.com/human-safety-toxicology-testing/our-testing-services/biocides/efficacy-studies-on-disinfectants-and-biocides/*

Accelerating biologics development programmes with phase-appropriate ready-to-use potency bioassays

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Biological activity of a biotherapeutic is a Critical Quality Attribute (CQA), which needs to be accurately measured by an appropriate potency bioassay during all phases of product lifecycle, from development to post-marketing approval. Regulatory agencies, such as the US FDA and EMA, have frequently noted that implementing a validated bioassay for potency testing in lot release is one of the most challenging and time-consuming activities, and should be initiated earlier in the biologic development programme. Key aspects of the assay design depend on the drug's mechanism of action (MOA), and should address phase-specific requirements. The inherent variability of biological drugs, as well as biological test systems such as cells, create significant challenges for establishing a robust bioassay in a quality control (QC) environment, and in ensuring long-term assay reproducibility. Hence, the design and implementation of a bioassay can be complex, costly, and take several months to years.

The growing urgency of delivering these life-saving therapies to patients faster is also driving the need for more efficient and fast approaches to design, validate, and implement mechanistically relevant analytical methods. Ready-to-use, qualified, cell-based potency assays reduce overall assay development time and programme costs. However, there are very few vendors that offer such ready-to-use solutions. Eurofins DiscoverX provides the most comprehensive menu of over 40 ready-to-use MOA-based bioassays that have been developed using stable cell lines and qualified with marketed innovator drugs, reference standards, or ligands. Each bioassay is based on the native biology of the drug target receptor and provides a receptor-proximal readout — in contrast to the distal readouts of phenotypic and reporter-gene assays — that is highly specific to that drug. The assay development strategy ensures that each bioassay meets the QC requirements for linearity, accuracy, precision, and robustness, and uses a simple, no-wash protocol that delivers results in 24–48 hours. These bioassays are available as complete kits, including cryopreserved cells and reagents required to run the assay, which facilitates faster and easy method transfer and implementation at the GLP testing sites. These bioassays can also be easily optimised for detection of neutralising antibodies in clinical samples.

Eurofins DiscoverX bioassays are successfully implemented in lot release testing of several marketed drugs both in US and EU. With the industry's largest off-the-shelf menu of qualified bioassays and assay development expertise, Eurofins delivers products and support to help take clients' drug to market, with confidence. For more information, visit: *www.discoverx.com/bioassay*

Take Eurofins PSS Insourcing Solutions home with you anywhere in the world

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Nearly 18 years ago, a client asked Eurofins Lancaster Laboratories to reverse its laboratory service model. He said, “You run great laboratories and have excellent HR practices, but there is some work we won’t outsource. Will you combine the two and come run our labs and bring your services in house?” At that moment Professional Scientific Services (PSS) was born.

From that initial client, who Eurofins PSS Insourcing Solutions still continuously serves, PSS has grown exponentially, expanding around the globe now managing the largest bio/pharmaceutical clients’ drug development programs at over 70 client sites and nearly 20 countries. PSS is a popular and trusted service model for clients who wish to keep proprietary testing in-house as an alternate to outsourcing work. Since Eurofins PSS hires, trains, and manages its employees to perform clients’ defined scope of laboratory services, clients are also able to focus on other drug development priorities.

In addition to Biopharmaceutical lab management, Eurofins PSS provides services in the Environment and Food industries from early phase research and development to finished product testing with expertise in all relevant global regulations. PSS teams not only set up and provide scientific services, but also find ways to do it faster, better, and more cost-effectively for clients through proactive KPI’s, a spirit of positivity, and LEAN continuous process improvements that generate cost savings. Clients challenged with the struggles of staff augmentation and attempting to hire and train temporaries, find this continuous service model, which is compliant with country laws, an astute business decision.

The PSS guiding principle is constant – find great people, take great care of them, so they in turn will take great care of clients. That’s why PSS has been recognised by clients with strategic partnership awards 12 times in the last 11 years.

Bringing nearly 60 years of GMP quality testing and in-house laboratory management expertise to clients’ global sites, award-winning PSS delivers compliant, co-employment free, and cost-effective services and gives clients the security of keeping their projects safely tucked away at any of their sites. With Eurofins PSS, clients enjoy the best of both worlds. For more information on how to pocket the power of PSS, visit: *www.Eurofins.com/PSS*

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