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BioPharma Services
News

BIO/PHARMA - MEDICAL DEVICES - COSMETICS - BIOCIDES

Eurofins BPT Toronto expands psychedelics testing and certification services to support mental health therapies

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Research on the use of psychedelics and natural or synthetic hallucinogenic drugs has seen considerable increase in recent years for medical therapies to manage significant psychological and behavioural changes in anxiety, mood disorders, addiction, substance abuse, PTSD and depression, which are on the rise.

The mind-altering effects of psychedelics as a therapy are currently being used in controlled environments to manage a number of psychiatric disorders, including the use of psilocybin-assisted treatment for alcohol addiction, MDMA (ecstasy) use for the treatment of post-traumatic stress disorder (PTSD), and LSD assisted therapy to improve mood and anxiety disorders, among several others.

The Food and Drug Administration (FDA) designated psilocybin-assisted therapy as a breakthrough therapy in 2019. And with the ever increasing number of clinical trials evaluating numerous other novel psychedelic treatment drug candidates, there is an increasing need for the development of suitable analytical methods, testing, and characterisation of the proposed psychedelic drug products.

Breakthrough therapy designations are intended to expedite the development and review of new drugs for serious or life threatening conditions. Regulatory agencies will often expedite approval for these “fast-track” or “breakthrough” designated therapies, but this requires a leading edge CRO who can meet these accelerated testing needs.

Eurofins BioPharma Product Testing in Toronto is authorised by Health Canada to provide GMP analytical services for testing controlled psychedelics such as psilocybin, psilocin, DMT, LSD, mescaline, 2C-B, and MDMA from medicinal mushrooms and hallucinogenic or synthetic psychedelic drugs.

Hallucinogenic active ingredients are controlled by Health Canada under Schedule III of the Controlled Drugs and Substances Act (CDSA). In order to legally possess and provide analytical services related to controlled substances, contract laboratories must be authorised by Health Canada with an applicable Dealer’s License.

A Dealer’s License from Health Canada is not limited to the possession, selling, production and transportation (i.e. importation/exportation) of controlled substances, but also includes testing. Eurofins BPT laboratory in Toronto is cGMP compliant and offers a range of analytical and regulatory solutions for psychedelics, including:

- Method development, transfer and validation
- Chemistry & microbiology release testing
- Onsite environmental monitoring
- Regulatory services: applications/submissions
- QA services: CAPA, SOPs, and GMP training
- Assistance with with compliance & regulations

For more information visit: *www.eurofins.ca*

Eurofins CDMO helps solve the rising challenge of colon drug delivery for biologics

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Due to the increasing incidence of inflammatory bowel disease (IBD), most commonly Crohn's disease and ulcerative colitis, colon delivery systems for oral administration have grown in popularity since the 1990s. Additionally, selective release of biologic drugs to the large bowel has been proposed as a viable strategy to enhance their oral bioavailability compared to gastric and/or small intestinal delivery via conventional peroral dosage forms.

Eurofins CDMO offers tailor-made solutions for biotech companies to deliver their biologic compound to the colon. Classical approaches are possible, which are based on pH-triggered polymeric coating of the dosage form (tablet, capsule or multiparticulate systems like pellets or mini-tablets). These coatings are resistant to acidic gastric pH and only dissolve and thus release the drug substance when the intestinal pH reaches a value of 6.5 to 7.0, typically in the ileocaecal region. Although this is a well-established technology, the drawback is that these coatings completely rely on the intestinal pH, which can vary from patient to patient, especially in those with IBD conditions. If the ileo-caecal or colonic pH does not reach the minimum value to dissolve the coating system, the drug release is incomplete or even zero. This results in a failure to deliver the drug as intended at the site of action.

Recently, more advanced systems can be offered. These are based on combining pH-triggered systems and enzymatically degradable systems, mostly polysaccharides. The dissolution of the coating is relying on two different mechanisms (pH or enzymatic), which results in a lower failure rate, compared to the single pH-triggered systems. These combinations are sometimes considered as fail-safe systems.

Research is currently underway at the Eurofins CDMO Ghent site (Belgium) to develop colon drug delivery systems for biologic drug substances. In addition to release characteristics, an extra challenge is the stability of the biologic drug substance, both in the dosage form and after release in the colon, where the biologic is often prone to enzymatic degradation. For more information: *www.eurofins.com/cdmo*

Organoids: the next step in precision oncology

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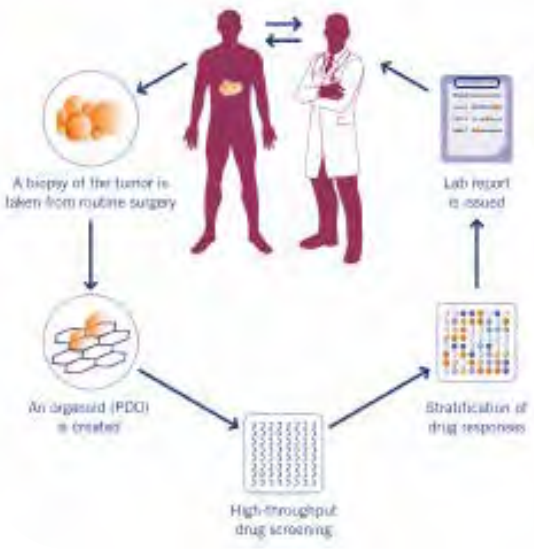
Each tumour is unique, and consequently, its treatment should be, too. However, too often many cancer treatments are "one-size-fits-all" and individual biological differences are not taken into account. In some cases, these standard treatments work, but in others they do not, and a trial-and-error approach is used until the best option is found. This process is exhausting for the patient, involves additional costs, and results in loss of critical treatment time.

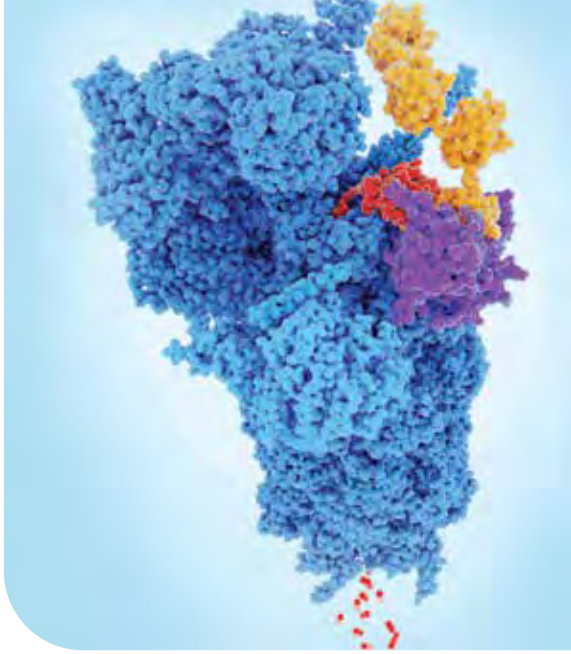
The implementation of next-generation sequencing (NGS) technologies and advances in bioinformatics have revolutionised the field of precision oncology, characterising the molecular differences between patients and tumours. The next step in personalised cancer treatment is the identification of the best therapy for each tumour.

The new Eurofins Onco-PDOTM service is a strategic approach targeting tumours that consists of taking a tumour sample and culturing these cells in a 3-dimensional laboratory system mimicking the human body environment, forming complex structures called PDOs (Patient-Derived Organoids). These PDOs are tested against different oncology treatments to assess their response. Two or three weeks from receipt of the sample, a detailed report is provided with the best personalised treatment for that tumour.

The Onco-PDOTM test is intended for patients who will be treated with different oncology treatments and is especially useful for those who have not shown response to first line therapy. To date, this test has been approved for breast, ovarian, colorectal, gastric, pancreatic, prostate, lung, and head and neck cancers, and it is in the process of being optimised for other cancer types.



This innovative approach provides an overview of how the tumour cells respond to standard oncology drugs under *in vitro* laboratory conditions, getting a sense of how that tumour would respond against those drugs in *in vivo* conditions. Thereby, organoids are the next step in personalised cancer treatment, determining the best therapy for each patient and each tumour, at different moments in time. For more information, visit: *www.eurofins-megalab.com/en/genetics-at-eurofins-megalab-professionals/*



The future of drug discovery: E3scan™ and beyond

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In the past two decades, a new paradigm-shifting approach to drug discovery has emerged. Targeted Protein Degradation (TPD) offers a different approach for drugging a disease target. Instead of inhibiting an interaction interface or catalytic activity, the molecular target is degraded. TPD uses small molecules to hijack the body's cellular degradation machinery by recruiting E3 ubiquitin ligases to proteins of interest, thereby inducing ubiquitin-dependent degradation of molecular targets. The potential of this novel approach is boundless, as it opens the door for the development of new chemical entities for proteins previously thought to be undruggable, including transcription factors, scaffolds, and other non-enzymatic proteins, which constitute 80% of the human proteome.

As a leader in drug discovery services, Eurofins Discovery launched its novel TPD service, E3scan™, in the middle of the COVID-19 pandemic. E3scan is based on previously established KINOME*scan*® technology, which utilises a substrate-recruitment, site-directed competition binding assay. The platform now includes assays against 12 different E3 ligases, as well as individual substrate recognition domains for substrate selectivity determination. This platform is being constantly refined and expanded with additional assays ready for launch in late 2021 and in 2022.

But what lies beyond the E3scan and the KINOME*scan* technology platforms? With this novel TPD space now rapidly evolving, almost every pharmaceutical company has a division in this space. Several pharmaceutical startup companies that were launched in the past few years are solely dedicated to the TPD space. Therefore, with so many different companies looking for degrader drugs for multiple new targets, the possibilities are endless for this area of drug discovery. The future of finding new drugs for targets that were previously considered to be undruggable is bright. In light of this, Eurofins Discovery is planning to remain the leader in drug discovery innovation, and will pursue the development of novel technologies and assays to support this exciting new era in drug discovery. These efforts will hopefully lead to the cure of many more human diseases. For more information, visit: *www.eurofinsdiscoveryservices.com/services/in-vitro-assays/protein-degradation/*

Eurofins BPT Italy expands biologics testing capacity with new fully operational BSL2 facility

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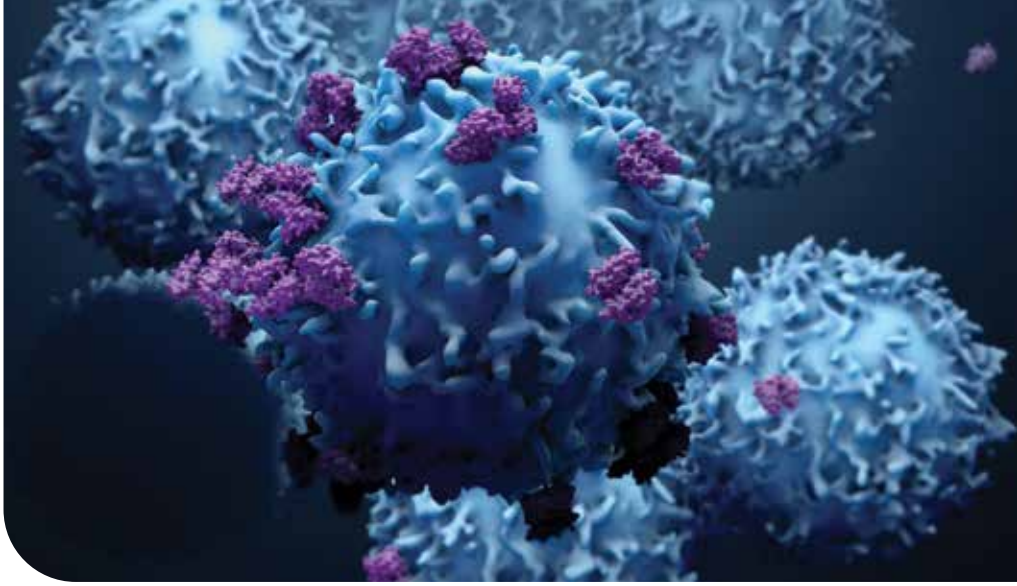
Drug modalities have grown increasingly complex over time: chemically derived small molecules were followed by biological medicines, and peptides, proteins, monoclonal antibodies, cell & gene therapy products are actually used more and more for prevention and/or treatment of diseases, including rare ones.

Biologics-based drugs have been increasing their market share over the last decade and according to many studies, global market size is expected to reach 750 billion USD in 2028, with a subsequent increased demand for manufacturing and testing processes outsourcing.

Eurofins BioPharma Product Testing Italy has been active in the testing of biologics for several years, and significantly invested in 2021 to increase capacity at its testing campus located in Milan, Italy, with the establishment of new laboratory space. Capacity at already existing laboratory space has also been increased, building new GMP facilities able to fulfil BSL2 requirements, with about an additional 1000 m^2 of net BSL2 GMP laboratory space, now fully operational.

The investment has been deployed in two phases: a 300 m^2 laboratory space has been established at warp speed and is fully dedicated to COVID-19 vaccine testing, active since early 2021. A new 700 m^2 facility was also built and completed at the end of 2021. To date, this represents one of the biggest BSL2 facilities among the Eurofins BPT global network. The facility is approved to facilitate testing Genetically Modified Microorganisms (GMMO) up to Level 2 and is ready to host molecular and cell biology tests, as well as biochemistry analyses. More than 40 analysts are currently active in this area with ambitious growth plans for the upcoming years. The facility comprises 11 testing rooms, with negative pressure cascades and H14 HEPA filtration, supporting a wide range of testing in microbiology, rapid sterility, mycoplasma, *in vitro* pyrogenicity, microbial identification, genetic sequencing, bioassays and viral safety, compendial chemistry testing, identification and quantification analysis, purity, impurities, contaminants, raw materials assessment, and physicochemical characterisation.

Thanks to the new fully dedicated GMP and GMMO BSL2 facility, Eurofins BPT Italy can support biopharmaceutical companies throughout the biologic lifecycle from analytical method development to marketed product release analysis with drastically increased capacity. For more information, visit *www.eurofins.com/bpt*



Eurofins Central Laboratory solves PBMC processing challenges in global clinical trials

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A peripheral blood mononuclear cell (PBMC) is any blood cell which has a round nucleus. This can include lymphocytes, monocytes, or macrophages. Many scientists conducting research in the fields of Immunology (including Autoimmune Disorders), Infectious Disease, Hematological Malignancies, Vaccine Development, Transplant Immunology, and High-Throughput Screening are familiar with PBMCs.

PBMCs are used in cell-based analytical assays, which may lead to many operational challenges with regard to specimen transport methods, isolation, speed, quality of isolation, freezing, and harmonisation to keep as many cells alive as possible for downstream analytical testing. Specialised downstream testing services include cell-based assays, flow cytometry, EliSpot, RNA/DNA isolation and sequencing analysis, protein extraction and quantification, and virology specimen stabilisation.

Eurofins Central Laboratory's global service offering delivers effective harvesting, processing, and analysis of peripheral blood mononuclear cells (PBMCs). This allows clients to evaluate immune functional responses to therapeutic agents and gain a deeper understanding of immune system function pre-dose, post-dose, and at other crucial stages of testing. The Eurofins BioPharma Services PBMC Network provides <10 hours TAT from point of collection to freezer, from most global site locations.

Eurofins Central Laboratory has established itself as the industry leader in global PBMC processing and has already expanded its global footprint to 30 qualified and harmonised laboratory locations worldwide, with new locations being added steadily based on new study requirements.

Eurofins' standard PBMC processing protocols include Ficoll Pacque Method, CPT Mononuclear Cell Preparation Tube and Accuspin PBMC Isolation Tube, and the teams have supported 25+ different sponsor-defined processing protocols that include variations in window of processing, collection techniques, washing steps, and specialised stabilisation media.

Eurofins Central Laboratory can incorporate sponsor-defined PBMC processing protocols via laboratory and technician qualification, including cellular viability. Training, harmonisation, and quality control are crucial to maintaining the integrity of PBMC processing to support global clinical trials. It is crucial to maintain the highest levels of quality at all stages of PBMC clinical laboratory testing, from specimen collection all the way through to processing, shipping, handling, storage, and analysis of the specimen. For more information, visit: *http://info.eurofinscentrallaboratory.com/pbmc-network*

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