eurofins | Advinus



Eurofins Advinus Limited

A perfect amalgamation of strong credentials providing best in class services and globally competitive offerings in the field of preclinical and clinical bioanalysis.

Eurofins Advinus is one of the oldest and renowned Contract Research Organizations headquartered in India. Eurofins Advinus is a multi-faceted contract research services company which has played a critical role in pioneering drug discovery in India and has extensive developed expertise and capabilities across a wider spectrum of services supporting companies in their pre-clinical and early clinical research. It is well recognized not only amongst its clients, but also within its peers and the regulators.

Over the years, data generated at the Eurofins Advinus facility has been successfully submitted by sponsors to regulatory agencies around the world including USFDA, Health Canada, EMA, MHRA (UK), HSA (Singapore), Medsafe (New Zealand), DCGI (India), Australia and AEMPS (Spain).

Eurofins Advinus has demonstrated its commitment to quality by receiving approvals from various GLP authorities including BfR (Germany), W&V (The Netherlands), NGCMA (India). The facility is also ISO 17025: 2005 certified for biological testing.

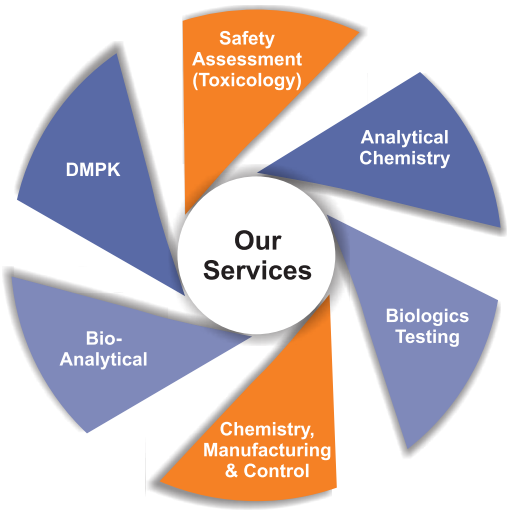
Eurofins Advinus is proud of its team which comprises of 400 people strong R&D organization. Our team not only possess strong expertise in various areas of contract research, but have a strong sense of commitment to quality and dedication to service the research needs of our clients, thereby acting as natural extensions of our client companies.

With a history of 25+ years of GLP compliance, Eurofins Advinus has had the privilege of working on several complex projects delivering impeccable service with on-time delivery.

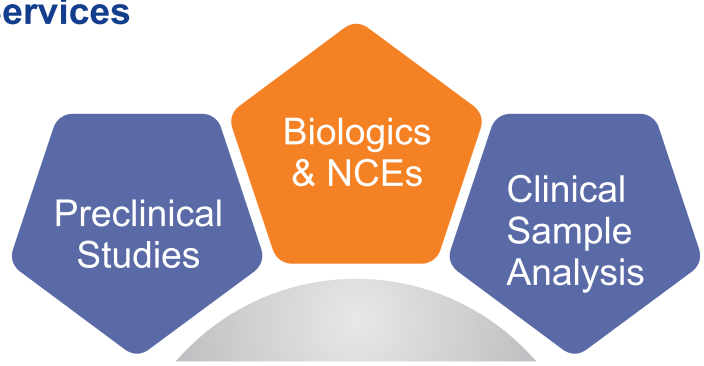
Our strong research orientation, problem-solving approach and commitment has earned us accolades and recognition from several large pharma companies. A testimony of this is our client list which includes companies such as Takeda, Merck, J&J, Novartis, Celgene and DNDi.

Eurofins Advinus has a track record of developing over 50 INDs for global regulatory submission by sponsors. We have conducted over 12000 regulatory studies for sponsors worldwide, extending services to the global pharma, agro and other allied industries.

Range of services offered by Eurofins Advinus



Bioanalytical Services



Eurofins Advinus has a unique offering in this area and offers an unparalleled combination of experience and laboratory resources.

The team possesses extensive expertise in various facets of bioanalytical testing such as developing sensitive methods using LC-MS/MS platforms-including analysis of multi-analytes, metabolites, pro-drug and active drug, endogenous compounds, nutraceuticals, plant extracts, photo/ temperature sensitive compounds, and racemic compounds using chiral chromatography and *ex-vivo* unstable compounds. Analytical methods for new chemical entities are routinely established and validated for rodent, non-rodent and human biological matrices. The laboratories are equipped with Watson LIMS™ 7.5 - a 21CFR Part 11 compliant data management system, and Phoenix WinNonlin 7.0 software. The lab also has on-site Quality Assurance (QA).

Our Expertise Include:

- Successful bioanalytical method development and validation of 300 plus compounds.
- Sample processing using precipitation, liquid-liquid extractions and solid-phase extractions optimized on a case-by-case basis
- Derivatization approaches e.g. for poorly ionizable compounds
- Developing methods for other matrices such as urine, feces, CSF, bile and various tissue homogenates.
- Methods for specialized formulations such as liposomes

Bioanalytical Services for Preclinical Studies:

- Method Development and Validation under GLP and as per requirements of USFDA and EMA guidelines to support GLP toxicology studies
- Fit-for-purpose method development for exploratory *in vitro* and PK studies

Bioanalytical Services for Biologics:

- Method development and Validation to support PK studies
- Method development and Validation to support immunogenicity studies

Clinical Sample Analysis:

- Development and validation of new analytical methods for NCEs using state-of-the-art LC-MS/MS & HPLC instrumentation and achieve sensitivity up to pg/mL levels.
- Validation of existing methods already developed in another lab for application to study sample analysis.
- Studies are performed in accordance with USFDA and EMA bioanalytical guidelines.
- Quantification of clinical trial samples for analyte and or metabolite(s) for Phase-I through Phase-III trials.
- Routine clinical samples such as blood, serum, plasma and urine are tested.
- Data can be turned-around within 72 hours of receipt of samples (along with preliminary PK analysis, if required) to support exposure-guided dose escalation studies.
- All logistics from clinical sites/ CROs are project-managed and we assure you hassle-free service of importing clinical trial samples to India.

Eurofins Advinus Limited
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