♦ |

Project Management

Dedicated Project Manager handling all queries & ensuring smooth operations

***** <u>Ē</u>. integrated information to improve decision making guaranteed continuity throughout the effective lines of communication & coordination commercial manufacturing process Ø Client Cross functional build strong relationship •1 with custome counter-par PM Technical Engineering Manufacturing R&D Quality Supply chain services Globally Accredited Contract Research Organization T BFR **GLP** Test Facility in dian GLP Authori (since 2005) German Health Ministry (1992-2011) W & V The Netherl (1999-2011) India OECD certified facility in india India received full adherent status OECD to Mutual Acceptance of Date from the OECD in March 2011 test facility For GLP studies submitted as part of IND 3 FD/2 to be audited by USFDA (2012 and 2016) GMP AAALAC OLAW certified facility in (since 2001) (since 2020 india ISO 17025:2005 for Medical Devices, biomaterials and ISO 9001:2015 for contract services in manufacture, test and stability study of Pharmaceutical intermediates, NCEs/APIS ISO ISO ophthalmic devices esting

Eurofins Advinus Limited

#21&22 Phase II, Peenya Industrial Area, Bengaluru 560058, India

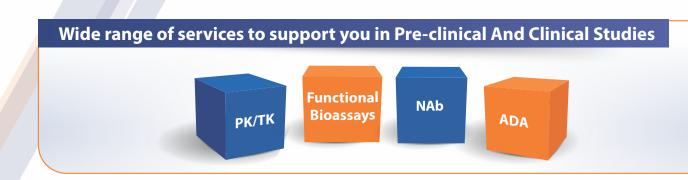
🛟 eurofins

Advinus



Custom Bioanalytical Testing for your Biologics Pipeline

- monoclonal antibodies
- novel biologics
- fusion proteins
- gene therapy products
- vaccines



Immunogenicity studies

Biologics like antibodies, enzymes and peptides are produced in living organisms through recombinant technology. Therefore, they can cause immune response in host which should be assessed carefully as it can lead to serious safety concerns.

- Develop and validate highly sensitive methods to detect low levels of Anti Drug Antibody (ADA) in presence of circulating drug under GLP setup
- Tiered approach [Screening, confirmatory, titre and Neutralizing Antibody (NAb)] for immunogenicity assessment following FDA Guidance
- Generate, characterize and label polyclonal antibody (for use as positive control, capture and detection) as per assay requirement

Regulated Bioanalysis (PK/TK) studies

- Develop or transfer and validate assay as per FDA guidelines that are specific, sensitive and customized for your biologic
- Generate critical reagents like antibodies for ٠ use as capture and detection
- Customized approach for various classes of biologics using different assay formats
- Fully functional GLP laboratory with 14 dedicated SOPs

Biomarker assays

Offering a range of protein biomarker services for all stages of research, from ready-to-run assays through to assay development and validation. Eurofins offers biomarker testing services which covers a broad range of the rapeutic areas.

Bioassays

Demonstrating potency and efficacy through biological functional characterization is an important factor for the success of a biologic product. This characterization is performed based on the mechanism of action of the biologic using assays such as ELISA, enzyme assays, signaling pathways, proliferation assays, CDC and ADCC.

Serological assays for Vaccines and Gene therapy products

We offer services for measurement of antigen specific antibody for evaluating novel vaccine and gene therapy products.

Allergio	Allergic reactions					
Anaphylactic reactions						
Reduction in efficacy						
Induction of	fau	utoimmunity				

Lavial Diala attac	Δ	ADA	NAb	Bioassay
Novel Biologics	A			
	B			
	С			
	D			
	E			
Fc Fusion Proteins	A	 		
	В			
Monoclonal Antibodies	A			
	В	 		
	С			
	D			
	E	•		
Peptides	A			
	В			
	С			
	D			

Polyclonal Antibody generation for

• Antigen: Biotherapeutic, full-length or truncated antibody, peptide

