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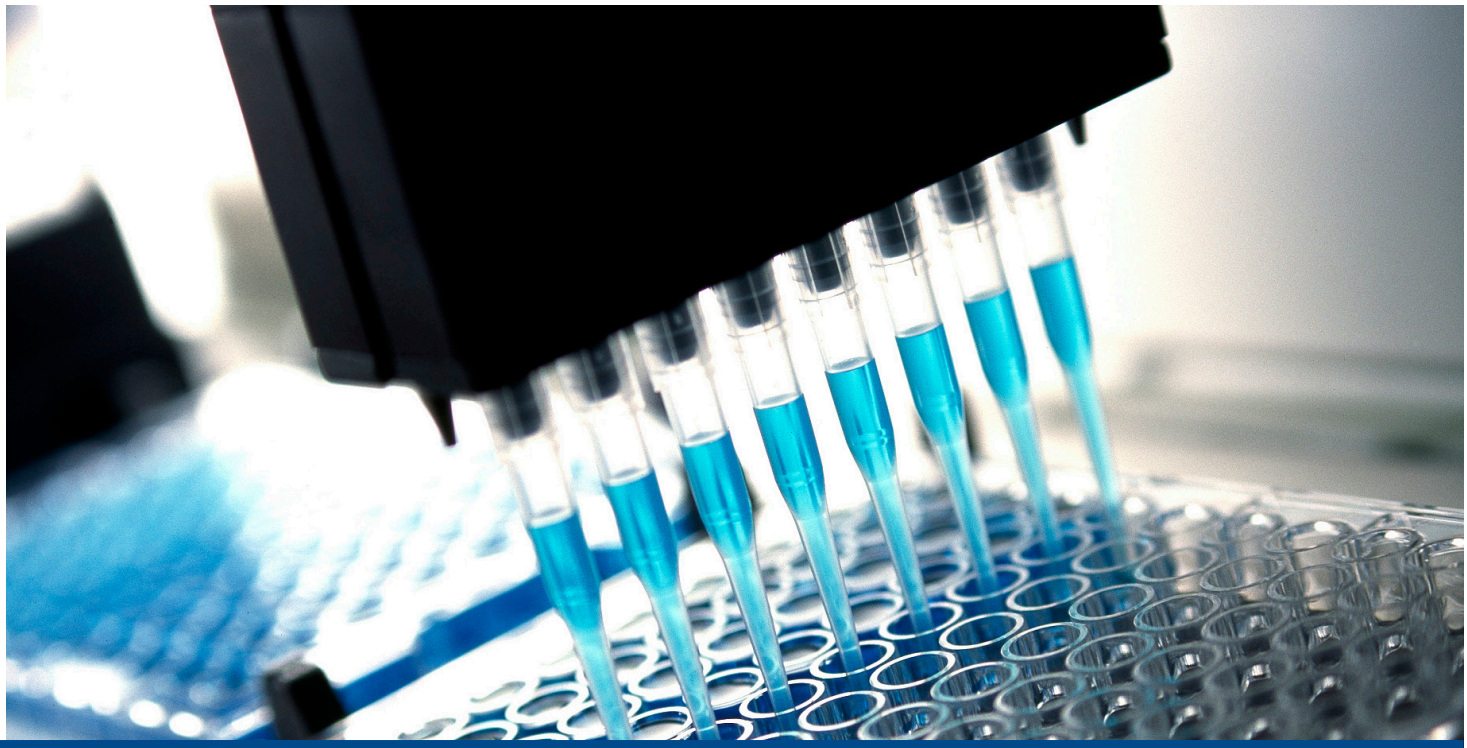

Preclinical and Clinical Services CRO

Pharmacelsus, Germany's market-leading preclinical and clinical services CRO, leverages expertise gained over 20 years of successfully finalising projects to provide the biotechnology and pharmaceutical industry with tailor-made drug discovery & development solutions.

Pharmacelsus offers G(C)LP and non-GLP studies for regulatory and exploratory demands. Our portfolio covers *in-vitro*, *in-vivo*, *ex-vivo* and bioanalytical support and services for biologics. We offer a number of unique assays addressing specific needs with tailored solutions.

All services are supported and complemented by our excellent bioanalytical department. Leveraging our high bioanalytical expertise, we quantify not only small molecules, peptide-based drugs and larger (bio)molecules, but also a large variety of relevant biomarkers.

Your Benefits

- Reliable partner with over two decades of experience
- 98% repeat business
- State-of-the-Art facilities
- Experienced and highly committed team of pharmacists, biologists, chemists and veterinarians with industry background
- Flexible handling of studies, tailored to our clients' requirements

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GLP CERTIFIED · Good Laboratory Practice · GLP GOOD LABORATORY PRACTICE

In-vitro ADME

- Physico-chemical parameters (solubility, stability)
- Stability in biological matrices and aqueous solutions
- Membrane permeability and transport (Pgp, Caco2, PAMPA, BBB)
- Protein binding (plasma protein binding, microsomal binding, binding to tissue)
- Drug interaction (CYP inhibition, CYP induction)
- Metabolism (CYP phenotyping, metabolic pathway identification)
- Metabolic stability/clearance

DMPK (All preclinical Species, non-GLP and GLP)**

- Cell fractions, hepatocytes (normal and slow metaboliser)
- Various study options e.g. snapshot PK, tissue distribution
- Complete workflow studies or stand-alone services: in-life phase, quantification, PK parameter calculation
- Additional services: metabolic cages, perfused or non perfused organs
- Biomarker quantification by LC-MS, Luminex®, Meso Scale Discovery (MSD) platform or ELISA

Toxicology Services non-GLP and GLP**

in-vitro:
2D & 3D cell culture models for exploratory approaches

- Short and long-term toxicity
- Basic: viability, membrane integrity, ATP content
- Mitochondrial, metabolite toxicity
- Immunotoxicity, histamine release
- Genotoxicity, AMES MPFTM Penta I test (non-GLP)

In-vivo:
All preclinical relevant species & studies necessary for submission

- Subchronic (DRF/MTD) & chronic toxicity*, acute toxicity*
- GLP & non-GLP bioanalysis of compounds & biomarkers

Bioanalysis of internal and external Samples

LC-MS:
(High Resolution – Q Exactive Plus, Triple Quadrupol MS)

- Small molecules, peptides and proteins
- Quantification in all matrices/cassette analysis
- Metabolite identification (Software Compound Discoverer™)
- Preclinical and clinical samples
- Non-GLP, GLP and GCLP
- Fit for purpose method development up to full GLP analytical validation

Biomarker analysis using multiplex systems (Luminex® and MSD platform):

- Biomarkers: immune, cancer, neurological, allergic, metabolic, etc.
- Bioactivity and toxicity assays
- Research grade studies up to regulated G(C)LP trials

In vitro and in vivo Pharmacology

- Cancer (In vitro efficacy & xenograft models)
- Immunomodulation e.g. histamine release, cytokine expression
- Kidney & liver health, e.g. fibrosis, NASH, quantification toxicity markers
- Diabetes & metabolic syndrome models

Services for Biologics (AB, ADC, etc.)

LC-MS (high resolution – Q TOF):
- Characterization: intact and peptide mapping/quality assurance
- Quantification
- Stability in biological matrices
- MSD platform (MESO QuickPlex SQ 120): Pharmacokinetics, Immunotoxicity, -genicity, -efficacy, High-throughput screenings

* Assays available in GLP format

** Services available in collaboration with our partner laboratories.