FULL SERVICES CATALOGUE

gem
FORlab

MIX DIFFERENT SKILLS AND CREATE YOUR PERFECT SOLUTION

PK - ADME

ADME: IN VITRO METABOLISM

- P450 induction (q-PCR; LC-MS)
- P450 inhibition (LC-MS)
- Plasma stability
- Hepatic clearance
- Renal clearance

Pre-Clinical

PROTEIN BINDING & STABILITY STUDIES

- Brain tissue binding
- Whole blood binding
- Plasma protein binding
- Blood to plasma ratio

Pre-Clinical

PERMEABILITY & TRANSPORTERS

- Caco-2 permeability
- MDCK-MDR1 permeability
- HaCaT permeability
- P-gP substrate identification
- P-gP inhibition

Pre-Clinical

BIODISTRIBUTION STUDIES

- Nucleic acid based drugs biodistribution
- Protein biodistribution (ELISA)
- NCE biodistribution (LC-MS)
- Immunohistochemistry
- Cell uptake

Discovery & Pre-Clinical

PD - TOX

PD: PHARMACODYNAMICS

- Biomarkers discovery & detection
- Biomarkers quantification
- Biomarkers validation

Discovery, Pre-Clinical & Clinical (I-III)

TOXICOLOGY

- Citotoxicity*
- Hemocompatibility*
- Genotoxicity (in vitro & in vivo)*
- Anti-drugs antibodies assay
- Cell viability

Discovery & Pre-Clinical

*See further

MoA & EFFICACY

IN VITRO MECHANISM OF ACTION

- Apoptosis & necrosis assays
- Cell chemotaxis

Discovery

IN VITRO EFFICACY

- In vitro enzimatic assays: development & validation (EC50 & IC50)
- Biologics binding specificity: IP-LC-MS identification
- MIC & MBC

Discovery

ANALYTICS

BIOANALYTICAL METHOD DEVELOPMENT/VALIDATION

- Quantitative & qualitative analysis of proteins in complex matrices
- Quantitative analysis of nucleic acids in complex matrices
- Quantitative analysis of small molecules & peptides in complex matrices

Discovery, Pre-Clinical & Clinical (I-III)

NBE/NCE CHARACTERIZATION

- HPLC-UV
- UPLC-UV-MS/MS
- Size exclusion chromatography (SEC)
- Cation exchange chromatography (CEX)
- Intact & reduced protein analysis
- Peptide mass fingerprinting (PMF)
- SDS Page on reduced & non reduced proteins
- 2D Page on reduced proteins
- Image analysis
- Western blotting

Discovery & Pre-Clinical

MED-TECH

IN VITRO DIAGNOSTICS

- IVD equipment, reagents & assays validation
- IVD analytical performance evaluation
- IVD clinical performance evaluation
- Clinical documentation revision (by Pathologist)

Discovery & Launch

MEDICAL DEVICE IN VIVO

- Skin sensitization (LLNA)
- Systemic toxicity (acute, sub-acute, sub-chronic & chronic)
- Rabbit pyrogen test (RPT)
- Implant toxicity
- Genotoxicity*
- Reproductive & developemntal toxicity

Discovery & GLP

*See further

MEDICAL DEVICE IN VITRO

- Chemical characterization
- Degradation testing
- Biodegradation of biopolymers
- Skin irritation (RhE)
- Permeation/absorption
- Toxicokinetic study: leachables & degradation products
- Cytotoxicity*
- Genotoxicity*
- Hemocompatibility*

Discovery & GLP

QUALITY CONTROL

PRODUCTION PROCESS QUALITY CONTROL

- Nucleic acids (mammalian, fungi, bacteria, virus)
- Exonucleases & endonucleases
- Endotoxins (LAL test)
- Mycoplasma
- Host cell DNA & proteins
- Conductivity
- Bioburden
- Surfactant residues (total, anionic, non ionic) + TOC
- Stability studies

Discovery & Launch

TOX ASSAYS

GENOTOXICITY IN VITRO

- AMES test
- HRPT gene mutation assay
- Mouse lymphoma assay (MLA)

Discovery & GLP

GENOTOXICITY IN VIVO

- Chromosome aberration test
- Micronucleus test

Discovery & GLP

CYTOTOXICITY

- XTT assay
- MTT assay

Discovery & GLP

HEMOCOMPATIBILITY

- Complement activation (SC5b-9)
- Leukocyte activation (PMN elastase)
- Hemolysis (cyanmethemoglobin)
- Coagulation (TAT & βTG)

Discovery & GLP

GENOMICS

GENOMICS

- Gene expression analysis (RT-qPCR, Microarray. NGS)
- DNA analysis (aCGH, NGS)
- Omics data analysis (Biostatistics & bioinformatics)

Discovery

FIELD STUDIES

FIELD STUDIES

- Field phase
- Method development, validation & application
- Analytical phase for residues detection & quantification

GLP

CHEMISTRY

ORGANIC CHEMISTRY

- Synthesis of chelating agents: DOTA, NOTA & other derivatives
- Functionalization of chelators with biomolecules & probes
- Synthesis method development & optimization
- Customized product synthesis (from mg to hg)
- Synthesis of APIs impurities
- Extraction & purification from complex matrices
- Conjugation: PEG, biotin, biomolecules & probes

Discovery & Launch

gem
FORlab