

LAXA

A SMALL MOLECULE CRDMO

that offers end-to-end solutions
to Pharmaceutical and Biotech
companies globally





Why LAXAI



State-of-the-Art Infrastructure



Integrated Discovery, Development and Manufacturing solutions



20+ Integrated Discovery Programs and 150+ CMC Projects



Strong Scientific team with vast experience in small molecule development



Leveraging AI in Drug Discovery and Development programs



Scale flexibility from pilot to commercial with seamless tech transfer



Focus on creating a sustainable supply chain



Handle complex chemistries with a high level of safety consciousness



Innovation focuses on green chemistry



100% regulatory and EHS compliance

Integrated Drug Discovery Services

We are one of the leading CRDMOs in India, delivering Integrated Discovery Services spanning Medicinal / Synthetic Chemistry, Biology, DMPK and Toxicology to large pharma and Biotech companies.

Integrated Drug Discovery Workflow

Target / Hit
Identification

Hit to
Lead

Lead
Optimization

Candidate ID /
Selection





Business Models

- Fee for Service (FFS) Collaborations
- Full Time Equivalent (FTE) Collaborations
- Flexible FTE Collaborations
- Risk Sharing Collaborations

Our Drug Discovery Capabilities



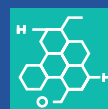
Hit Identification

- Structure based virtual screening
- Ligand based virtual screening
- Fragment based Hit Identification
- Library Design and Synthesis
- De Novo Design of Analogues
- Scaffold design for hit identification (ID)
- In vitro and In vivo studies



Lead Generation

- Preliminary IP analysis on newly designed scaffolds
- Synthesis of focused libraries for LG and LO
- Structure based design and synthesis
- Fragment based discovery
- e-ADME analysis
- QSAR



Lead Optimization

- De Novo Design and Optimization
- Off-target screening
- Physicochemical properties
- in vitro biology & ADME-Toxicity
- SAR development
- PK and safety profile of chemical lead



IND Enabling Studies

- Dose-range-finding studies
- Tox batch Scale up
- Informal stability studies
- Geno Tox studies
- MTD and GLP Tox Studies
- Pre-formulation and formulation support

Chemistry Capabilities



Synthetic Chemistry

- Antibody Drug Conjugates
- PROTAC and Molecular Glues
- Peptides, Polypeptides
- Lipid Chemistry
- Boronic acids
- Carbohydrates / Oligosaccharides
- Nucleotides / Oligonucleosides
- Asymmetric synthesis
- Scaffolds, Building blocks synthesis
- Diversified Library design & Parallel synthesis
- Deuterium (stable label) compounds
- Impurity / Metabolite synthesis
- Reference standards and Key Intermediates



Process R&D

- Route Scouting
- Fit for purpose Process development
- Process safety studies
- Non-GMP material supplies for Tox studies
- IND filing support



Analytical Capabilities

- Phase appropriate analytical method development
- GLP method development and validation
- Prep HPLC purification of chiral / achiral / non UV active compounds
- Kinetic, photo and thermal stabilities
- Physical characterizations (DSC, TGA, XRD, ICP-MS)
- Impurity profiling & Reference standard characterization





Following services offered through our preferred partners

- Biacore- Binding studies
- in vivo models in oncology, inflammation, metabolic disorders and CNS

Biology Capabilities



Notable Achievements

- Oncology: 3 programs (2 Integrated Projects, 1 IND Candidate)
- Inflammation: 4 programs (2 Integrated Projects, 2 Milestones, 1 Clinical Candidate)
- Metabolic Disorder: 1 Integrated Project



Target Classes

- Kinase
- Transcription factor
- GPCR
- Proteases
- Nuclear receptor
- Esterase



Service Capabilities

- Custom Assay Development and High Throughput Screening (HTS)
- MoA Studies employing molecular & cell biology techniques
- Wide array of cancer cell lines
- Blood Based Assays
 - Macrophage Polarization
 - Cytokine Profiling
- Gene Cloning
- CRISPR Modifications
- Cell line development



Assay Technologies

- nanoBRET
- alphaLISA
- HTRF
- LanthaScreen
- HiBit
- ADP Glo
- Fluorescence polarization
- LCMS/MS based enzymatic hydrolysis and cellular uptake assay



Leading Therapeutic Technologies Handled

- Targeted protein degradation (PROTAC)
- Peptide based prodrugs including brain and immune cell specific delivery
- Dual pharmacology
- Antibody drug conjugate

DMPK and TOX Capabilities



Physicochemical Screening

- **Solubility**
 - Kinetic Method
 - Thermodynamic method
- **Stability**
 - In fresh plasma
 - In fresh blood
 - In biorelevant media
 - Chemical stability across pH



Permeability

- PAMPA
- Caco-2
- MDCK-MDR1



Metabolism

- **Metabolic Stability**
 - Liver microsome (mice, rat, dog, monkey, human)
 - Hepatocytes (mice, rat, dog, monkey, human)
 - Liver S9 fractions (mice, rat, dog, monkey, human)
- **Met-ID in vitro and in vivo**
- **Time dependent CYP inhibition**
- **CYP inhibition (two-point or IC50 determination)**
- **CYP Induction & CYP profiling**
- **GSH Trapping**



Pharmacokinetics

- Mice (Balb/C, SAM, 57BL/6, nude)
- Rats (Sprague Dawley and Wistar)
- Beagle dogs, Rabbits (New Zealand white)
- Hamsters (Golden Syrian) & Monkeys (Cynomolgus)
- **Dose escalation studies** in rodents, rabbits, hamsters, dogs
- **Repeat dose PK study** in rodents, rabbits, hamsters, dogs
- **Cassette dosing/Snap-shot PK**
- **CSF collection in rats/dogs**



Excretion

- In rodents using metabolic cages with cold compound
- Biliary excretion in rats



Distribution

- Protein binding (equilibrium dialysis)
- Tissue distribution in rodents (using cold compound)
- Assessment of blood-to-plasma ratio



DMPK and TOX Capabilities Cont.



Geno Toxicology Studies

- Ames
- Micronucleus
- Chromosomal Aberration



Toxicology Studies

- MTD in rodents, dogs
- 7-/14-Day repeat dose tox in rats, dogs
- 28-Day repeat dose tox (GLP) in rats, dogs



Pre-formulation Capabilities

- Nano-suspension, solid dispersion, SMEDDS, micro-emulsion, co-solvent to improve bioavailability
- Excipient compatibility studies
- Salts selection and screening
- Polymorph screening
- Solid state characterization (DSC, TGA, pXRD etc)
- Stability studies of API or drug product as per ICH guidelines



Chemical Process Development

State-of-the-art facility and a well established development team ensuring that we have the resources and expertise to assist your program in the most efficient and cost-effective manner.



Our Capabilities



Process Development Capabilities

- Route Scouting
- Fit-for-purpose development
- Process design, optimization
- Design-of-Experiments (DOE)
- Impurities Fate and Purge studies
- Genotoxic Imp Risk assessment
- CMC / IND filing support



Process Engineering Capabilities

- Process intensification lab.
- Process Simulation and Modeling
- Piloting studies
- Scale up and Tech transfer



Analytical Capabilities

- Phase appropriate analytical method development
- Method Validations and Transfer
- Forced Degradation Studies
- Impurity identification and characterization studies.
- Reference Standard Qualification
- Regulatory documentation support
- Stability studies (informal and ICH)



Process Safety Capabilities

- Early Hazard Identification
- HAZOP Studies
- Safety Assessment
- Thermal Scanning
- Reaction Calorimetry (RC1e)
- Differential Scanning Calorimetry (DSC)
- Powder Safety Testing



Solid State Studies

- Polymorph identification
- Crystallization studies
- Solubility studies
- Solid state Characterization
- Salt Screening studies



Analytical Equipment

- 400 MHz NMR
- LC-MS, GCMS/HS, UPLC-MS
- UPLC- ELSD
- HPLC-UV/ Fluorescence
- HPLC-UV (DAD)
- Bruker D8 - P-XRD
- ICP-MS/ OES
- Particle size analyser (Malvern-3000)
- GPC Equipment

Manufacturing Capabilities

LAXAI provides comprehensive manufacturing services with global standards for Specialty Fine Chemicals, KSM, RSM and Drug Substance.



Manufacturing Capabilities

With our deep-rooted commitment to quality, safety, and compliance, along with our production capabilities and scientific knowledge, we are a reliable partner for all of our clients' manufacturing requirements.

We offer a wide range of services, including but not limited to:

- Tox Batch
- First-In-Human (FIH) - GMP Batch
- Late Phase - Tech Transfer and Process Validation
- Custom Manufacturing
- Quality Assurance and Regulatory Support
- Etherification
- Diazotization & Hydrolysis
- Sulfonation
- Hydrogenation
- Fluorination
- Alkylation
- Nitration
- Amination
- Bromination
- Chlorination
- Cryogenic reactions at -80°C to -100°C
- High temperature reactor - > 200 to 300° C
- HVD reactor - < 0.5 Torr
- Hydrogenator – up to 1400 PSI
- Oxidation, Reduction and Cross coupling
- Plug Flow Reactor – Continuous Flow Development





Quality & EHS

- Quality standards: complies with ICH Q7 section 19
- Uncompromising cGMP quality coupled with phase appropriate adaptability
- Accredited by stringent regulatory authorities
- SCADA (Supervisory control and data acquisition) system for data management
- Zero Liquid Discharge Facility
- 100% EHS Compliance



Global Accreditations

FDA U.S. FOOD & DRUG
ADMINISTRATION



Ministry of Public Safety
and Security



Cofepris
Comisión Federal para la Protección
contra Riesgos Sanitarios

Medicines &
Healthcare products
Regulatory Agency



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