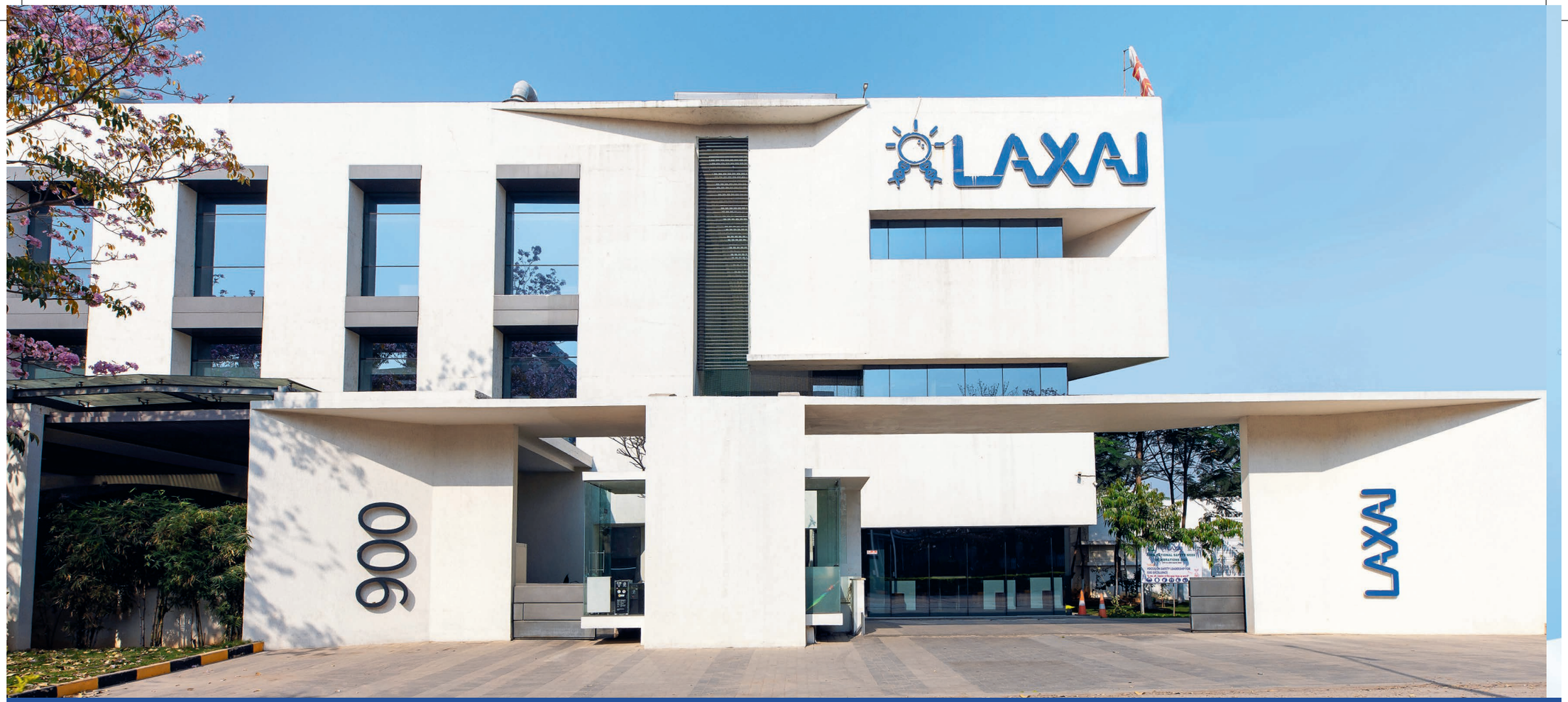
LAXAI

A SMALL MOLECULE CRDMO

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

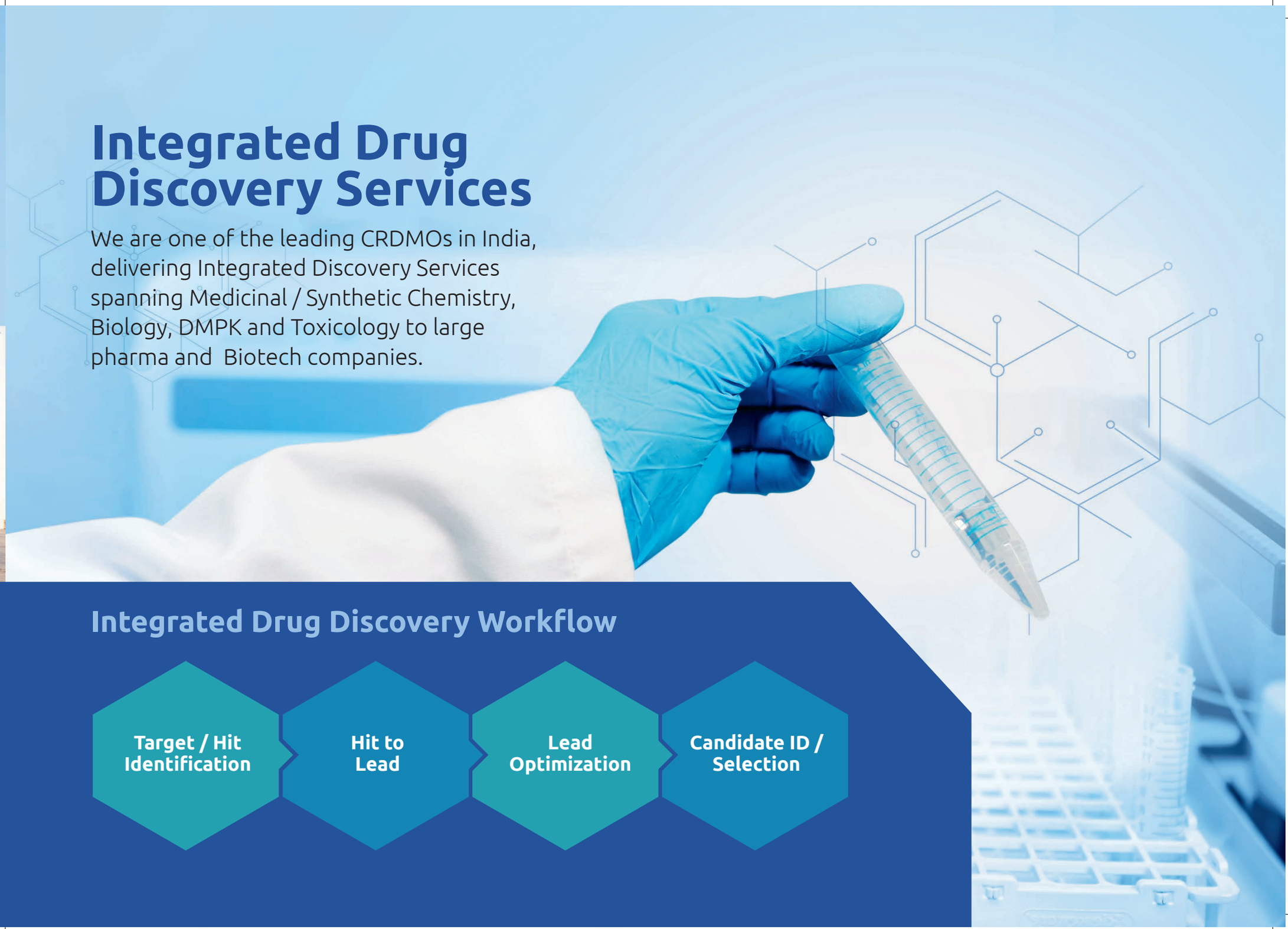


Why LAXAI

- 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 Capabilties

- 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

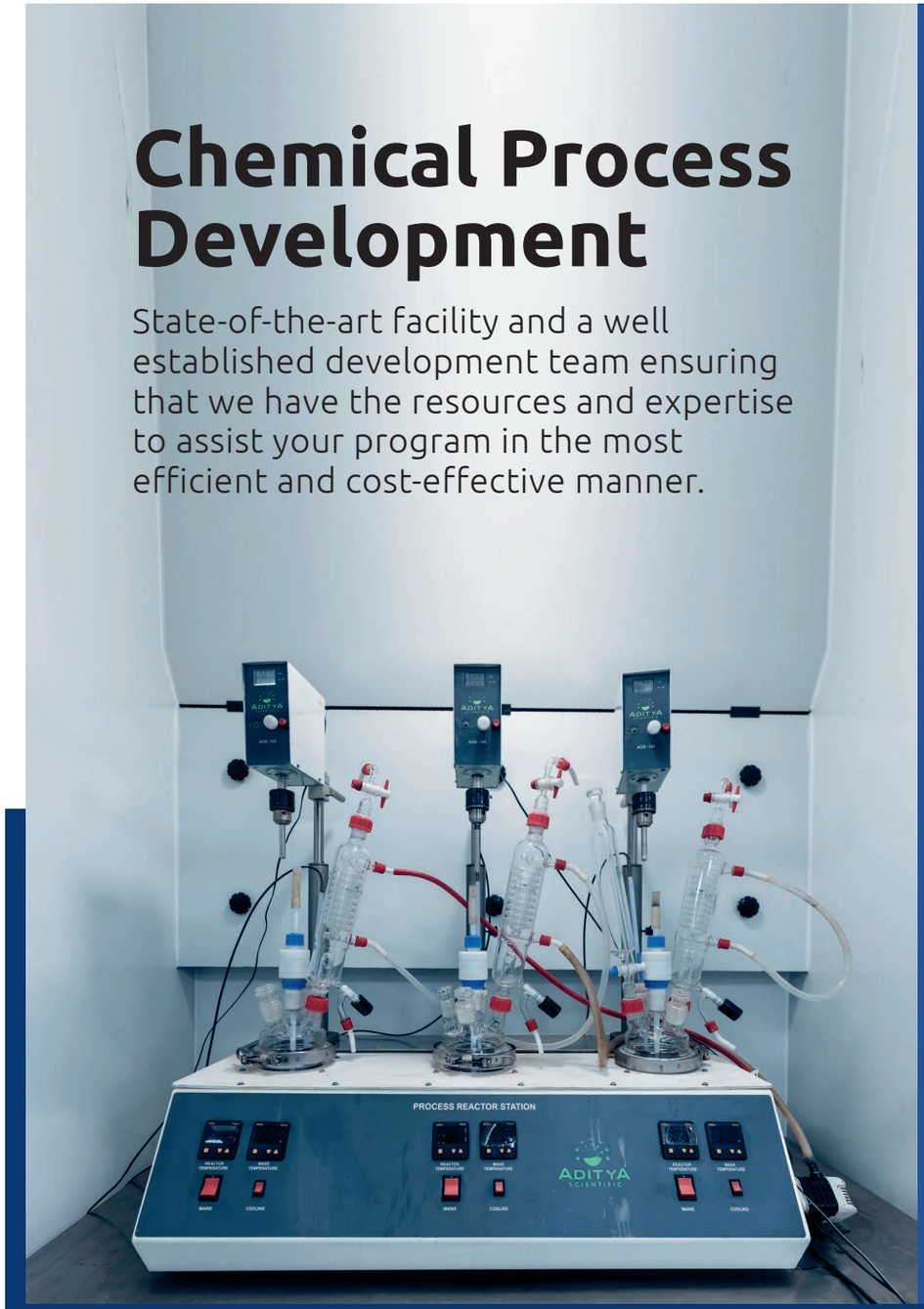
- MTD in rodents, dogs
- 7-/14-Day repeat dose tox in rats, dogs
- 28-Day repeat dose tox (GLP) in rats, dogs

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 Safety Capabilities

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

Process Engineering Capabilities

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

Solid State Studies

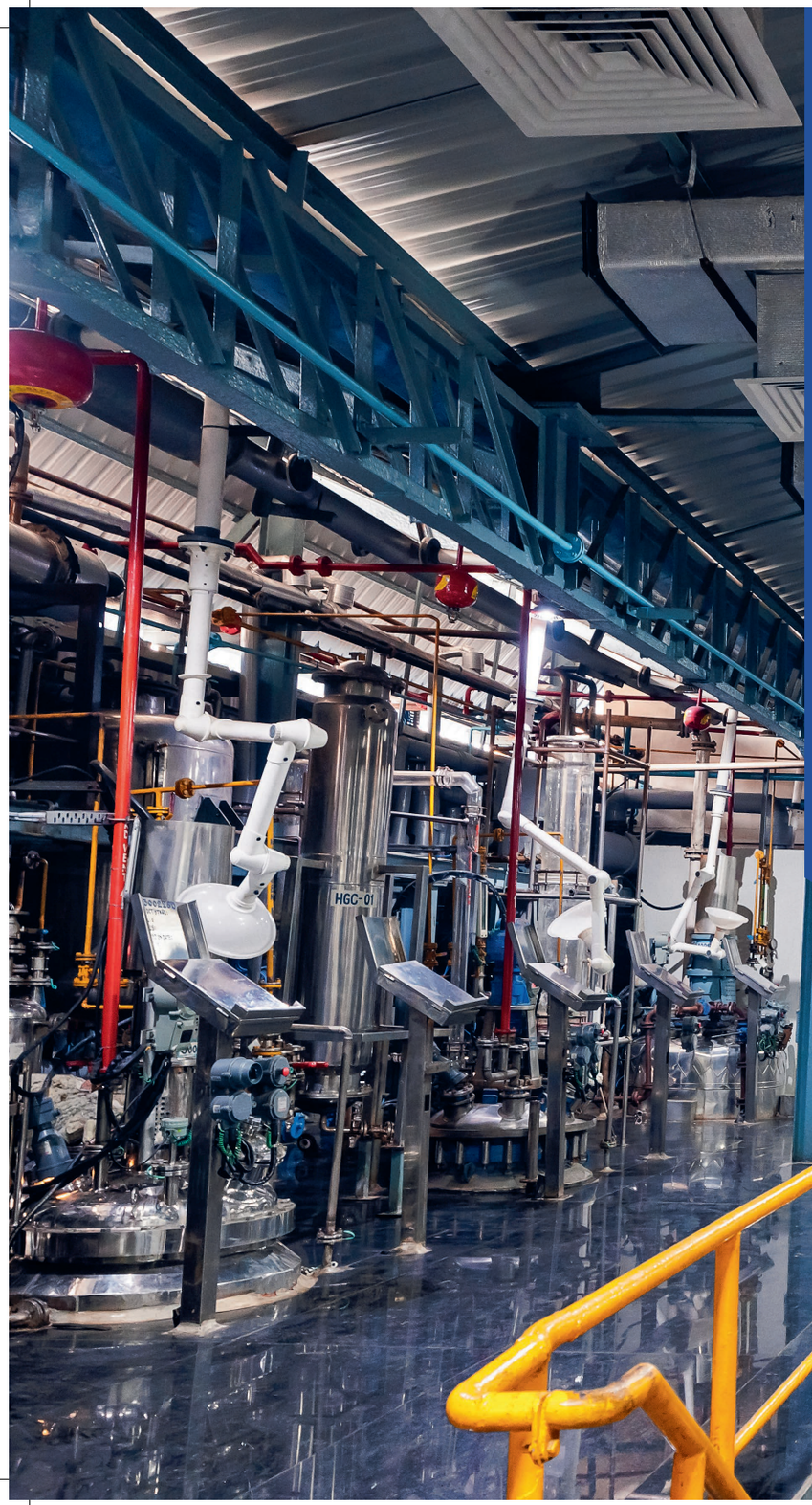
- Polymorph identification
- Crystallization studies
- Solubility studies
- Solid state Characterization
- Salt Screening studies

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)

Analytical Equipment

- 400 MHz NMR
- LC-MS, GCMS/HS, UPLC-MS
- UPLC- ELSD
- HPLC-UV/ Fluorescence
- HPLC-UV (DAD)
- Brucker 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.

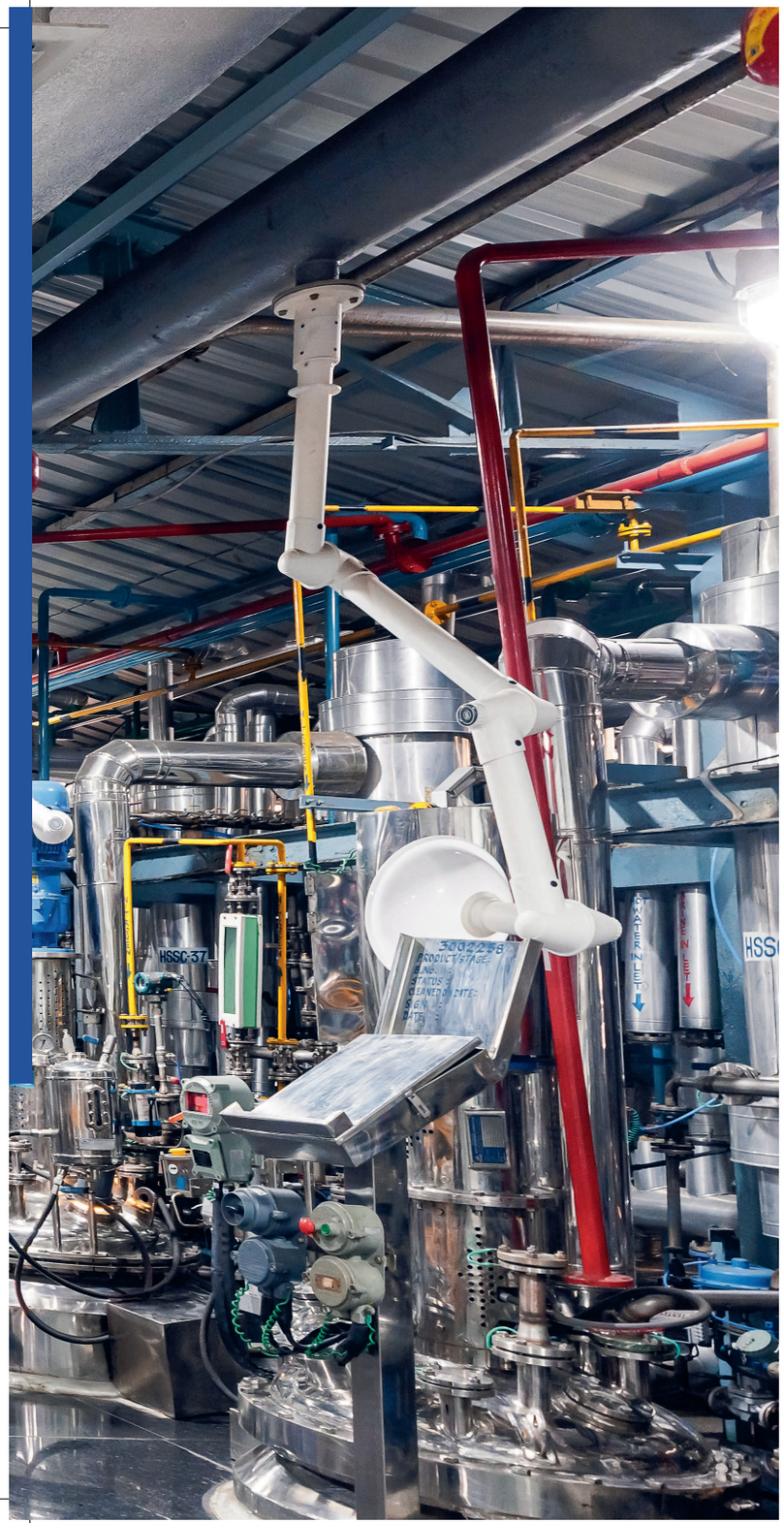
We offer a wide range of services, including but not limited to:

- Tox Batch
- First-In-Human (FIH) - GMP Batch
- Late Phase - Tech Transfer and Process Validation
- Custom Manufacturing
- Quality Assurance and Regulatory Support

Manufacturing Capabilities

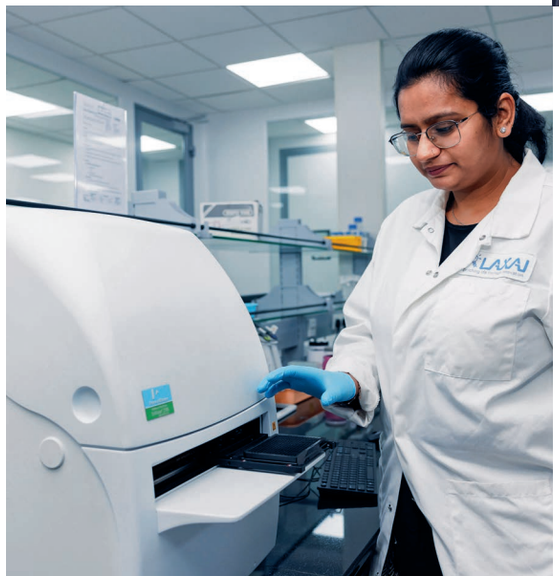
With our deep-rooted commitment to quality, safety, and compliance, along with our production capabilities and scientific knowledge, we are a reliable partner for all of our clients' manufacturing requirements.

- 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

U.S. FOOD & DRUG ADMINISTRATION

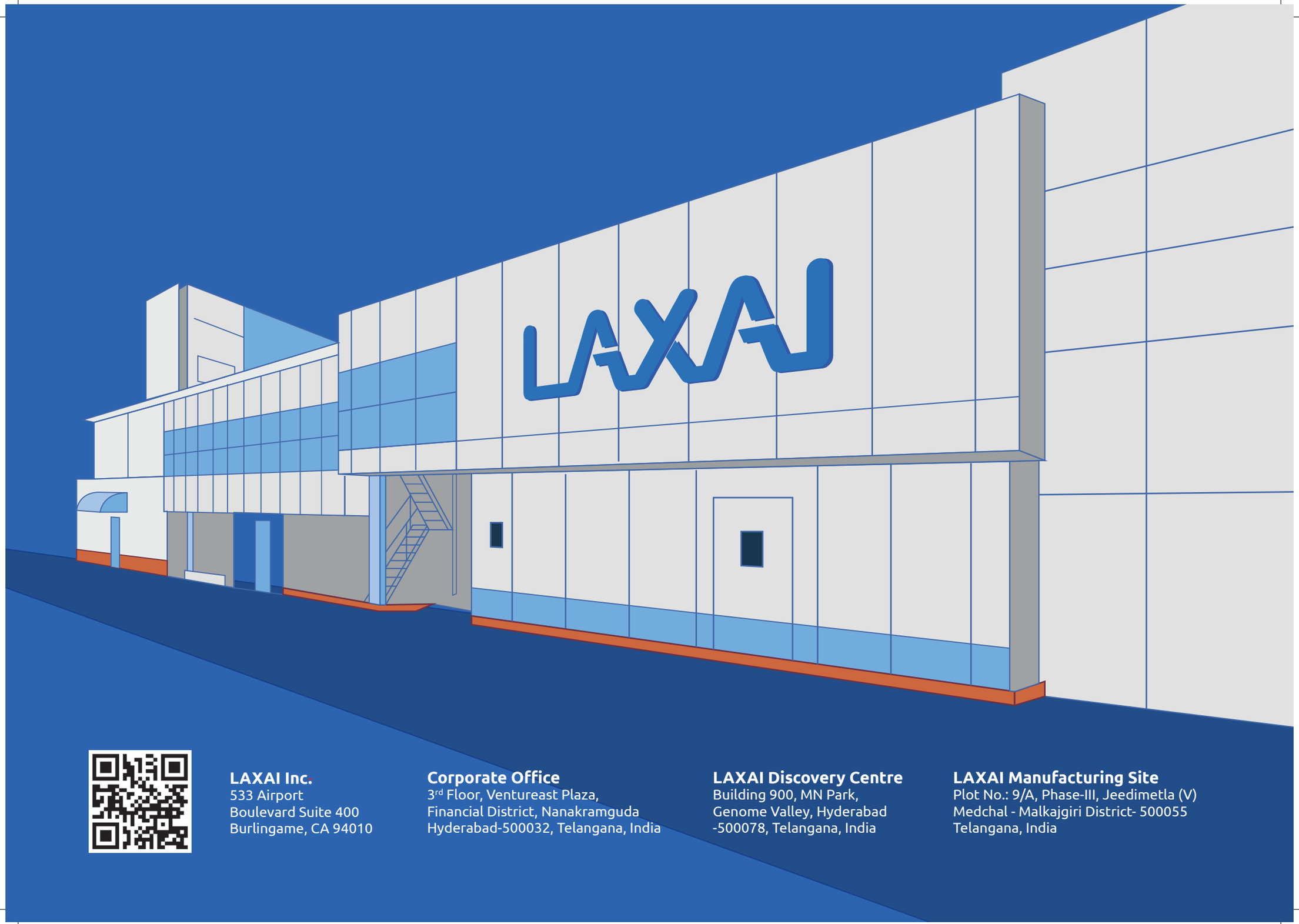
pmda

Ministry of Public Safety and Security

edqm

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Medicines & Healthcare products Regulatory Agency



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