

Chemistry Services

Medicinal Chemistry

- Hit Identification
- Lead Generation
- Lead Optimization
- Computational Chemistry

Synthetic and Specialty Chemistry

- Synthesis of Reference Standards
- Scaffold & Building Blocks Synthesis
- Analogue Compounds for Lead Optimization
- Stereoselective Synthesis
- Complex Chemistry

Design and Synthesis of Libraries

- Structure -based Designing Methods
- Ligand -based Designing Methods
- Structural Biology
- De -Novo Design
- Validation
- Stability Studies
- Quality Control

Process Scale -up

- Route identification
- Process Optimization
- Pre -Selection
- Custom Synthesis from gram to multi-ton

Analytical Services

- Method Development
- Chiral Separation
- SFC Technology
- Purity & Integrity (High - throughput)
- Physicochemical Profiling
- Metabolite Identification

Differentiators

- No Conflict model: GVK BIO has no internal programs
- The IP /Confidentiality of Customers is well protected
- Proven ability to Scale from mg to kg level at one location
- On-line project tracking
- E-Note book reporting
- Chemistry complemented by expert services in Biology and Computational Chemistry
- The largest SAR manually curated database with 4 million compounds available
- Comprehensive technical team with relevant Pharmaceutical, Biopharmaceutical, and Academic experiences
- State of the art Analytical instrumentation with experienced Analytical research scientists
- Highly qualified and experienced team

Business Models

Full Time Equivalent (FTE)

Fee for Service (FFS)

Standalone Services

Milestone Based

Integrated Services

Medicinal Chemistry

- **Hit Identification:** Hit Series are developed using advanced chemical analoging. GVK BIO can work with the sponsor generated hit or with the hit generated in-house using computational chemistry.
- **Lead Identification:** GVK BIO develops hit series based on potency, Chemical tractability, ADME properties and novelty. Of this, the best series are advanced to Lead Optimization.
- **Lead Optimization:** Compounds are designed and synthesized not only to improve the potency but to improve ADMET features. The compound selected can potentially undergo GLPTOX followed by IND filing.
- **Computational Chemistry:** Our team provides insights into analog design, virtual screening, de novo design, library enumeration, ADMET models and PK modeling.
- **Medicinal Chemistry (Integrated Services):** Leveraging on the extensive expertise that GVK BIO has in Biology, Informatics and Chemistry, we accelerate your drug discovery projects to IND.

Synthetic and Specialty Chemistry

Our well-trained and experienced chemists have the capability to deliver custom synthesis projects including reference standards, analogues and specially designed lead molecules. We take up specialty chemistry projects in Stereoselective Synthesis, PEGylation, Carbohydrate, Small Peptides, Large Scale Hydrogenation, Ozonolysis, Dendrimers, Nucleosides and synthesis of radio labeling compounds using cold isotopes such as ^2H and ^{13}C .

Design and Synthesis of Libraries

Utilizing our strength in Medicinal and Computational Chemistry, we design and synthesize lead-like, drug-like fragment and molecule libraries to enrich chemical space of our client's compound repository. Some of the methods / models adopted are:

Structure-based Designing Methods

- Analysis and Modeling of Target Protein Structures
- Virtual Screening Models
- Fragment-based Design

Ligand-based Designing Methods

- QSAR Models
- Pharmacophore Models
- Generation of Drug-like & ADME/ Toxicology Filters
- Library Generation

Process Scale-up

GVK BIO along with its associate company, Inogen Labs, is well equipped to advance your lead compounds from lab-scale through kilo/pilot to commercial production with speed and efficiency. The GVK BIO/Inogen Process R&D team consists of more than 135 chemists committed to the highest quality and regulatory standards.

- Route Development & Synthesis on Lab Scale
- Process Development, Optimization & Validation
- Laboratory Scale Up, Engineering Studies including Hazard Evaluation
- Process Analytical Development Support
- Impurity Profiling
- Stability Studies (ICH)
- Documentation for regulatory filings
- Kilo Lab reaction volume ~ 1200 L
- Pilot Plant reaction volume ~ 8200 L
- Manufacturing Block reaction volume ~ 140,990 L
- Cryogenic Capability up to -70°C , Hydrogenation up to 20 Bar & High Temperature up to 200°C
- WHO cGMP approved and Zero liquid discharge site

Analytical Services

We provide Analytical Services to Pharma and Biotechs globally. A full service spectroscopy group is available with state-of-the-art high resolution MS and high field NRM equipment for impurity identification. Semi-preparative and preparative services are also available.

- Normal and reverse phase method development
- Method validation
- Forced degradation studies, including photo-degradation, diastereomeric and enantiomeric purity determination
- Preparative isolation and identification of intermediates, impurities, and by-products
- Spectral characterization / identification by MS and NMR techniques
- Stability protocol design and execution
- SFC chiral separation capability
- Polymorph and Salt Screening