



Integrated Solutions across the R&D  
and Manufacturing Value Chain

**GVK**  **BIO**  
Accelerating R&D

## About us

GVK BIO is a global Contract **Research and Development** Organization (CRDO) providing scientific services to the global life sciences industry. Established in 2001, GVK BIO supports the research and development programs of our customers. We enable our customers to bring their products to market in a fast yet cost-efficient manner. GVK BIO employs a no-conflict model and ensures no internal programs that can potentially conflict with our customers projects. Our team of over 2500 well qualified scientists, backed by rigorous processes, scalable practices, modern facilities and a strong customer-centric partnering approach, makes it India's leading CRDO. We are headquartered in Hyderabad, India with operations in seven state-of-the-art research facilities: five in India and two in Morgan Hill, California.



## Our Solutions

### Large Molecule R&D

**Aragen Bioscience, Inc.**, a wholly-owned subsidiary of GVK Biosciences Pvt Ltd; is headquartered in Morgan Hill, California. It is recognized for providing excellent preclinical data of sound scientific quality, with data driven flexibility in the execution. With advanced degrees from reputed institutions, Aragen Bioscience scientists perform complex projects in the following areas:

- Cell Line Development: Short timelines and high titers with **RapTr** CLD services (CHO DG44 and CHO-GS)
- Antibody Development: Catering to wide range of therapeutic and diagnostic targets
- Protein Sciences: Gene synthesis to expression, purification and process development
- Protein Analytics: Characterization, formulation and stability studies
- Preclinical Efficacy Testing: *In Vivo* disease models-fibrosis, oncology, RSV and many others along with associated *In Vitro* and *Ex Vivo* assays

### Small Molecule R&D

#### Chemistry

- Diversity in Chemistry capabilities
- 25,000+ compounds being synthesized at different scales in a year
- 15+ years of organization experience in handling different Chemistries

#### Biology

- Hit to Lead → Lead Optimization → Clinical Candidate Nomination
- *In Vitro* Pharmacology - DMPK - *In Vivo* Pharmacology - Toxicology
- Disease area depth in Oncology, Pain, Inflammation and Metabolic diseases

#### Integrated Drug Discovery

- Hit and Lead Generation
- Lead Optimization

#### Drug Repurposing

- Drug Centric, Disease Centric and Target Centric Repurposing

## Discovery Solutions

GVK BIO provides a continuum of drug discovery services from pre-hit to candidate selection. Our expertise spans across numerous therapeutic areas with a focus on Oncology, Pain, Inflammation and Metabolic diseases. We leverage our expertise in Chemistry, Biology, CADD, ADMET/PK and animal disease models to provide a customised and truly integrated model for drug discovery leading to pre-clinical candidates. We have a proven track record of providing cost-effective, innovative and efficient solutions towards delivering clinical candidates for our collaborators.

## Chemical Development Solutions

GVK BIO offers a spectrum of Chemical Development Solutions through convenient, single-site distribution of infrastructure, thereby delivering a seamless and innovative transition of solutions from lab to pilot plant and bulk manufacturing, with speed and quality. We ensure quality in the process during the design and development phase by understanding the Critical Process Parameters (CPP) and Critical Material Attributes (CMA).

### Our value proposition:

- 10+ years of experience in process R&D of complex molecules, with relevant regulatory approvals
- 10 + IND filing support per year
- 125+ projects in the last 3 years | 70+ projects in preclinical and Tox stage

### Our key customer offerings:

- Early to late phase drug development
- Safe and QbD-based process optimization
- Quality and On Time In Full (QOTIF) delivery

## Formulation and Analytical Solutions

We help customers in overcoming challenges faced during development by identifying risks and mitigating them timely. Our capabilities includes:

- Preformulation studies
- Formulation development
- Analytical method development and validation
- Impurity profiling and trace metal analysis
- Physicochemical characterization
- Stability and photostability testing

## Contract Manufacturing Solutions

We offer long-term Contract Manufacturing Solutions in development, validations, DMF filing, manufacturing of New Chemical Entities (NCE), Key Starting Materials (KSM), Active Pharmaceutical Ingredients (API) and Intermediates. Our manufacturing expertise is designed to handle a wide range of operating conditions in commercial scales. With two locations - **Hyderabad and Visakhapatnam**, we have exhibited exemplary process and technology for NCEs, progressive drugs and commercial production of advanced Intermediates/APIs. Our process development, technology transfer and commercial execution teams collaborate seamlessly to provide concept to commercialization timelines. Our key strengths include:

- Two locations - Hyderabad and Visakhapatnam
- Develop robust and cost-effective process
- Expertise in handling hazardous reactions like Cyanation, Chlorination and high pressure reactions
- Zero liquid discharge facility



Ministry of Food and  
Drug Safety





Leading Small Molecule CRDO



Large Molecule Discovery Partner



## **GVK<sup>BIO</sup>** **Accelerating R&D**

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