Leading Small Molecule **CRDO**

GVK BIO

Large Molecule Discovery Partner

ARAGEN

GVK BIO
Accelerating R&D

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Integrated Solutions across the R&D and Manufacturing Value Chain

GVK BIO
Accelerating R&D

About us

GVK BIO, a leading Contract Research & Development Organization **CRDO** that services the global Biopharma industry; is headquartered in Hyderabad, India with operations in four sites including California, USA. Established in 2001, GVK BIO has over 16 years of rich experience across the Research and Development value chain with a focus on speed and quality. Our team of over 2000 highly qualified scientists, backed by well-defined and scalable processes, modern facilities and a strong customer-centric partnering approach, focus on bringing our customers' products to market.

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 & 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 delivering a seamless and innovative transition of services from lab to pilot plant and bulk manufacturing. We build the required quality into the process during the design and development phase by understanding the Critical Process Parameters (CPPs) and Critical Material Attributes (CMAs).
Our value proposition:

- >10 years' experience in process R&D of complex molecules, with all relevant regulatory approvals
- >10 IND filing support | year
- >125 projects in the last 3 years | >70 in pre-clinical | ToX

Our key customer offerings:

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

Our Solutions

Large Molecule R&D

Aragen Bioscience Inc, a 100% subsidiary of GVK Biosciences is recognized for scientific quality and flexibility bringing over 150+ combined years of industry experience. With Doctorates from reputed institutions, Aragen Bioscience performs complex projects in following areas:

- Cell Line Development: short timelines and high titer with **RapTr** CLD services (CHO-DHFR and CHO-GS)
- Antibody Discovery: Catering to wide range of therapeutic and diagnostic targets
- Protein Sciences: Gene synthesis to expression, purification and process development
- Pre-clinical Efficacy Testing: *In Vivo* disease models – fibrosis, oncology, RSV and many others | *In Vitro* testing – bioassays
- Formulation and Stability Testing

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* - DMPK - *In Vivo* Pharmacology – Toxicology
- Disease area depth in Oncology, Pain & Inflammation & Metabolic diseases

Integrated Drug Discovery

- Hit & Lead Generation, Lead Optimisation

Drug Repurposing

- Drug Centric Repurposing, Disease Centric Repurposing, Target Centric Repurposing

Formulation & 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 & Validation
- Impurity Profiling & Trace Metal Analysis
- Physicochemical Characterization
- Stability & Photostability Testing

Contract Manufacturing Solutions

We offer long-term Contract Manufacturing Solutions in development, validations, DMF filing, manufacturing of New Chemical Entities (NCEs), Key Starting Materials (KSMs), Active Pharmaceutical Ingredients (APIs) and Intermediates.

Our manufacturing expertise is designed to handle a wide range of operating conditions with flexible 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:

- Diverse Scientific team
- Two locations - **Hyderabad & Visakhapatnam**
- Seamless technology transfer
- Develop robust & cost-effective process
- Expertise in handling hazardous reactions like Cyanation, Chlorination, High Pressure reactions
- Zero Liquid Discharge facility
- Environment friendly routes under GMP conditions