

# Contract Manufacturing Solutions



GVK BIO offers 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. We have flexible business models to support various client needs:

- a. Process optimisation, technology transfer, validations and DMF filing followed by manufacturing upon commercialization
- b. Technology development, validations, DMF filing support and commercial manufacturing
- c. Technology absorption and commercial manufacturing

Our manufacturing expertise is designed to handle a wide range of operating conditions with flexible scales. Our commercial manufacturing facility is co-located with our pilot plant, providing end-to-end API solutions from feasibility phase in R&D to commercial launch. Our process development, technology transfer and commercial execution teams collaborate seamlessly to provide concept to commercialization timelines.

GVK BIO's manufacturing facility at Hyderabad has approvals from worldwide regulatory authorities like **USFDA, EDQM, PMDA, KFDA and WHO**. These accreditations facilitate faster and easier approvals of DMFs/dossiers for our business partners.

## Regulatory Approvals



Ministry of Food and  
Drug Safety

## Zero Liquid Discharge facility



# Manufacturing Infrastructure

## Unit-I @ Hyderabad

- Six GMP production blocks: Reaction volume of 177 Kilo Liters (m<sup>3</sup>)
- Reactor capacities: 20 L to 6000 L
- MoC: Stainless steel, glass lined, all glass, Halar coated, Hastelloy-C etc.
- Hydrogenation capabilities: 50 L to 2,000 L, up to 25 bar; Large scale Column Chromatography
- Class 100,000 cleanrooms; Kilo labs & powder processing area
- QC Lab with stability chambers & microbiology
- USFDA, EMEA, EDQM, PMDA, MFDS, WHO GMP
- Dedicated HPAPI lab with suitable reactors, isolators; Final API handling is done in a glove box; Commercial manufacturing facility will be initiated soon



## Unit-II @ Visakhapatnam

- Two GMP production blocks: Reaction volume of 87 Kilo Litres (m<sup>3</sup>)
- Reactor capacities: 100 L to 6000 L
- MoC: Stainless steel, Glass lined, all glass, Halar coated etc.
- DCS based dispensing of solvents, automated hydrogenation facility
- Class 100,000 cleanroom; Kilo lab & powder processing area
- QC lab including stability chambers



Leading Small Molecule CRDO



Large Molecule Discovery Partner



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