GVK BIO
Accelerating R&D

# Contract Manufacturing Solutions


GVK BIO offers long term Contract Manufacturing Solutions in development, validations, DMF filing, manufacturing of New Chemical Entities (NCEs), Active Pharmaceutical Ingredients (APIs) and Intermediates. We have flexible business models to support various client needs:

a. CRDM (Contract Research & development, Manufacturing): Technology development & optimization, transfer, validations, and DMF filing, followed by commercial manufacturing.

b. CRD (Contract Research & Development): Technology development, optimization, and technology transfer.

c. CM (Contract Manufacturing): 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 supplies, including DMF support. 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, WHO GMP.** These accreditations facilitate faster and easier approvals of DMFs/dossiers for our business partners.

## Regulatory Approvals

FDA · edqm · pmda · Ministry of Food and Drug Safety · DNV

# Manufacturing Infrastructure

## Unit 1 @ Hyderabad

- Seven GMP production blocks: Reaction volume of 169 Kilo liters.
- Reactor capacities: 20L to 6000L ranging from -90°C to + 180°C.
- MoC: Stainless steel (SS-316, SS-304), Glass lined, All glass, Halar coated and Hastelloy-C.
- Hydrogenation capabilities: 50L to 2000L; Large scale column chromatography.
- Class 100,000 cleanrooms; Kilo labs and powder processing area Reactor capacity : 20L to 2000L.
- QC Lab with stability chambers and microbiology.
- USFDA, EMEA, EDQM, PMDA, MFDS and WHO GMP.
- HPAPI lab & production block with isolators.
  - OEL limit; 1-10 micro gram/m³.
  - HPAPI QC testing lab.
- Zero Liquid Discharge Facility to handle the effluent.
- Process engineering & safety evaluation lab, equipped with (TSU, DSC, RC, and other miniature version of powder processing equipment).

## Unit-II @ Visakhapatnam

- Two GMP production blocks: Reaction volume of 82 Kilo liters.
- Reactor capacities: 100L to 6000L Utility capacity ranging from -90°C to +170°C.
- MoC: Stainless steel (SS316), Glass lined, All glass and Halar coated.
- DCS based dispensing of solvents and automated hydrogenation facility.
- Class 100,000 cleanroom; Kilo lab and powder processing area.
- QC lab including stability chambers.