



**GVK BIO- Integrated Solutions across the R&D Value Chain**

**SAFETY AND  
COMPLIANCE FIRST,  
BUSINESS LATER**

# GVK BIO – A Group Company Of GVK Conglomerate

Among the top 25 business groups in India, with diverse business interests and a committed investments of over \$20B.

Life sciences



Hospitality



Airports



Energy







Resources

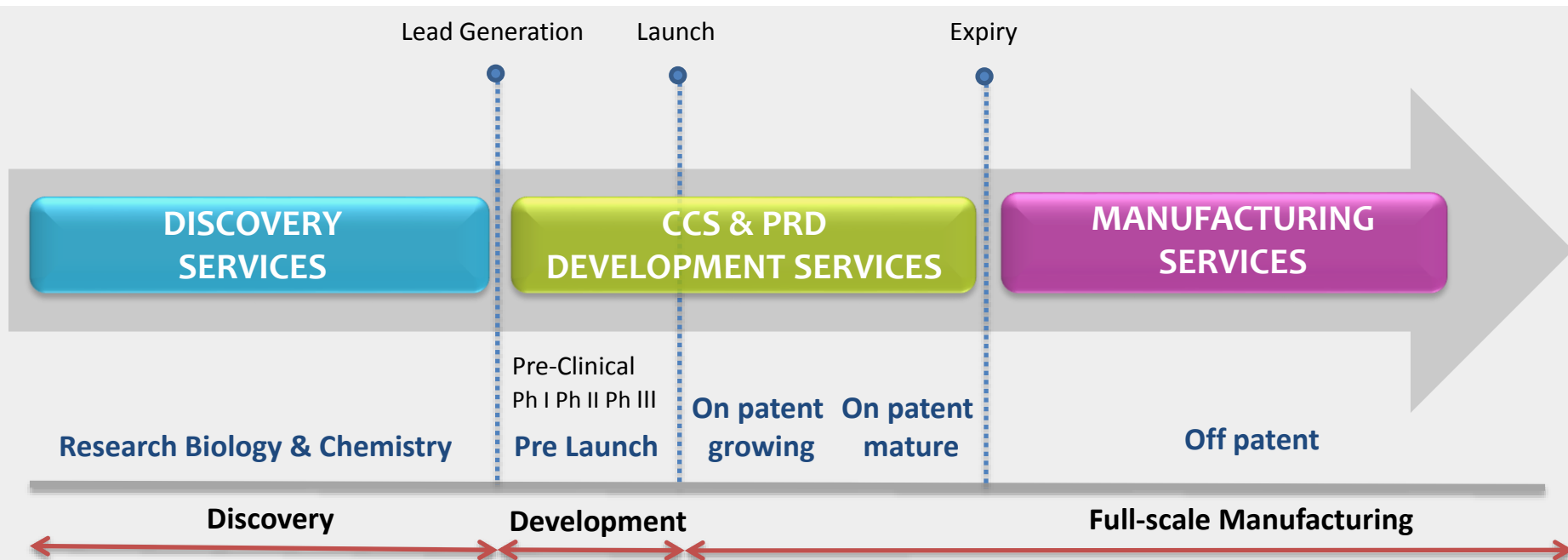


Transportation



# GVK BIO- Overview

-  Asia's leading Integrated Discovery Research, Development and Manufacturing organization, established in 2001
-  A large pool of scientific talent, over 1500 scientists and 200 PhDs
-  350+ clients globally
-  State-of-the-art infrastructure spread across 45 acres of land



# Services across the R&D value chain

## DISCOVERY



### Small Molecule R&D

- Chemistry
- Biology

### Biologics (Large Molecule)

- Antibody generation
- Cell line development
- Bioprocessing

### Integrated Programs

### Drug Repurposing



## DEVELOPMENT



### Process R&D

### Custom Chemical Synthesis

### Bio and Chemo Catalysis

### High Potent APIs

### Carbohydrate Chemistry

### Analytical Services

### Formulation R&D Services

### Regulatory Support



## MANUFACTURING



### Contract Manufacturing

### Electronic and Fine Chemicals

### Process Validations and DMF Filings

### Commercial APIs and Intermediates





## **Synthetic Chemistry**

Custom synthesis, Asymmetric synthesis, Organometallics

## **Specialty Chemistry**

Agrochemicals, Carbohydrates, Chiral chemistry, Nucleosides & Nucleotides, Peptides, Electronic grade chemicals (OLED precursors), Organoboron chemistry

## **Library Synthesis**

Library design, Solution phase, Solid phase, Scavenging through resins, High throughput purification, Compound management

## **Isotope Synthesis**

Incorporation of  $^{14}\text{C}$ / $^3\text{H}$  and labeled  $^{14}\text{C}$ / $^3\text{H}$  alkyl groups

## **Medicinal Chemistry**

Hit generation, Lead identification, Lead optimization

## **Computational Chemistry**

CADD, Virtual screening, *In Silico* prediction of binding potentials, ADME-PK properties & drug likeness, hERG liability, Homology model

# Biology Services

## ***In Vitro* Pharmacology**

- Reagent generation
- Assay development
- Medium & high throughput screening

## ***In Vivo* Animal Models**

- Oncology
- Pain/Inflammation
- Metabolic disease
- Safety and toxicology

## **DMPK Services**

- Physicochemical characterization
- Absorption/Transporters
- Distribution
- Metabolism
- PK studies
- Tissue distribution with cold compounds
- Other specialized assays



# Large Molecule R&D Services

## **Antibody Discovery**

Antigen design, Hybridoma development, Complex screens, Humanization

## **Protein Production**

Cloning, Transient and stable expression, Purification

## **In Vitro Testing**

Protein binding, Affinity and activity; Bio-conjugations

## **Animal Models**

In Vivo models for a wide range of indications including oncology, fibrosis, pulmonary, BSL-2 Infections, Autoimmune and custom models

## **Stable Expression**

Royalty free CHO platform for novel and biosimilar biologics

## **Bench Scale Process Development**

Upstream: Cell culture and Downstream: Purification

## **Formulation and Stability Testing**

Thermal stability and formulation studies





# Integrated Programs

## Hit Generation

Virtual Screening, High-throughput Screening, Fragment Based Screening

## Hit Validation

## Lead Generation

Identification of potent and selective compounds with desirable PK features

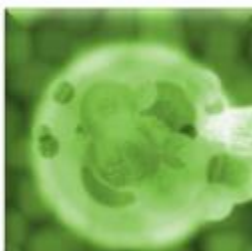
## Lead optimization

Optimization of efficacy, PK and safety profile to deliver a pre-clinical candidate



- |  |   |   |
|--|---|---|
| <ul style="list-style-type: none"> <li>• Project feasibility</li> <li>• Reference compound synthesis</li> <li>• Assay development</li> <li>• Potency/ADME</li> <li>• Profiling of reference compounds</li> <li>• Virtual library design</li> </ul> | <ul style="list-style-type: none"> <li>• Medicinal Chemistry</li> <li>• Informatics</li> <li>• <i>In Vitro</i> potency</li> <li>• Selectivity</li> <li>• In-depth ADME, PK, <i>In vivo</i> efficacy</li> <li>• Exploratory Tox</li> </ul> | <ul style="list-style-type: none"> <li>• Patent filing</li> <li>• GLP/GMP manufacturing: PMDA</li> <li>• Metabolism</li> <li>• Met ID characterization</li> </ul> |
|--|---|---|

### Focus Therapeutic areas:



Oncology



Metabolic



Inflammation



Pain

# Drug Repurposing Services

Drug Centric Repurposing

Disease Centric Repurposing

Target Centric Repurposing

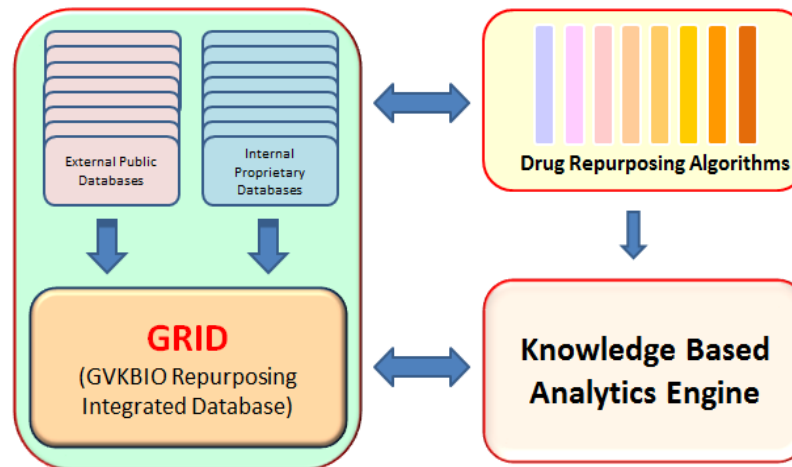
## GVK BIO Repurposing Integrated Platform (GRIP):

An in-house developed repurposing platform that helps expedite drug repurposing activity.

### Components of GRIP:

- GRID: GVK BIO Repurposing Integrated Database
- Drug repurposing algorithms
- Analytical tools
- Visualization engine

- Database covers proprietary and public databases
- Team comprising of data analysts with expertise in drug discovery
- Capability to provide end-to-end solutions from *in-silico* data analysis, to pre-clinical services and clinical services



GRIP - GVKBIO Proprietary Drug Repurposing Platform



# Process R&D and Custom Chemical Synthesis

## Early phase drug development

Early phase development of NCE or KSMs, by efficient Process Research & Development, scale up and supply of material with GMP/CMC documentation suitable for the clinical phase

## Process Research and Development

POC to development of innovative, cost competitive, operationally feasible, eco-friendly, regulatory and intellectual property compliant robust processes

## Custom Synthesis/Contract manufacturing of NCEs/ KSMs/ APIs

From process accommodation to cost competitive and regulatory compliant commercial manufacturing with YOY efficiency improvement

## Biotransformation, Homogeneous and Heterogeneous catalysis

Screening, optimization and scale-up services



# Analytical Services

Discovery

Medchem

Preclinical

Drug Candidate

IND

Phase I to III

**Analytical method development and validation of non-chromophoric and high molecular weight compounds using detectors like PDA, RI, ELSD & FLD**

**Identification and characterization of impurities using hyphenated techniques like LCMS/GCMS, 2D NMR**

**Assessment, method development and quantification of genotoxic impurities as per the guidelines**

**Quantification of trace metal analysis by ICP-MS as per USP <232> and <233>**

**Thermal analysis and solid state characterization using pXRD, DSC, TGA etc**

**cGMP compliant stability studies as per the ICH guidelines**

**Isolation and purification using semi prep HPLC and SFC**



# Formulations R&D Services

Pre-formulation development  
 Formulation development  
 Analytical R&D  
 Reformulation services  
 Stability studies  
 Pre-clinical & clinical supplies  
 Manufacturing of exhibit batches

## Dosage forms:



Tablets



Capsules

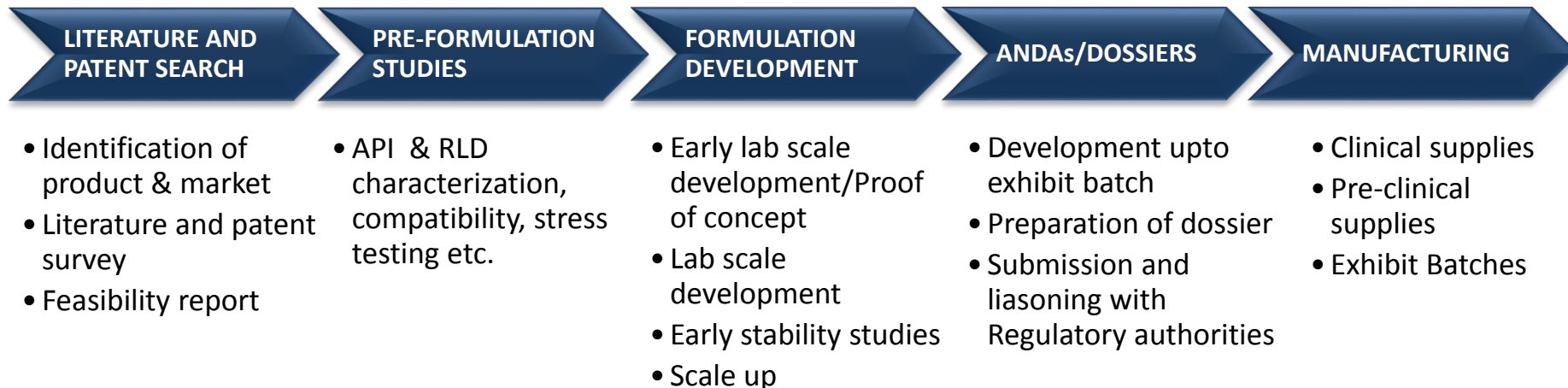


Semi-solids



Ophthalmics and  
Injectables

## Integrated Formulation Development Solutions



# Manufacturing Services

## cGMP Manufacturing

- New Chemical Entities (NCEs)
- Key Starting Materials (KSMs)
- Active Pharmaceutical Ingredients (APIs)
- Intermediates

## Commercial APIs and Intermediates



- cGMP compliant six manufacturing blocks with varied capacities ranging from 20L- 6000L
- **Total reaction volume capacity:** 170,000 L
- **MOC:** All glass, glass lined, SS & Hastelloy reactors
- **Hydrogenation capabilities:** 50 L to 1000 L upto 25 bar and large scale column chromatography
- Class 100,000 cleanroom, kilo labs and powder processing area
- Stability chambers for conducting stability studies at all conditions

## Global Accreditations:



**350+** customers worldwide  
**16** of the top **20** big **Pharmaceutical** companies  
Small and virtual **Biotechnology** companies globally

## Client Speak

“ GVK is a great group of scientists. The chemistry they perform is outstanding and they are very efficient in providing materials in the quantities required and in a timely manner. We are very happy overall with the performance and productivity of GVK.

### European Mid Pharma

“ We have very high expectations for the performance of the CRO (timelines, quantity, productivity etc.) and GVK BIO meets these expectations. Communication with the project manager is excellent and is a key element in making the collaboration a successful one.

### Big Pharma

“ GVK has demonstrated a good level of chemical synthesis expertise. GVK BIO has been very responsive and the communications are timely and regular.

### Leading Agrosience Company

# Resources

> 1,200,000 Sq. ft. of lab & manufacturing infrastructure spread across 45 acres of land



Discovery Services-  
Campus I (Hyd)  
135,680 Sq.ft

Discovery Services-  
Campus II (Hyd)  
140,000 Sq.ft

Discovery Services-  
Campus III (Hyd)  
24,000 Sq.ft

Discovery Services-  
Campus IV (Bengaluru)  
100,000 Sq.ft

Manufacturing  
& Development (Hyd)  
535,000 Sq.ft

Manufacturing  
Services (Vizag)  
170,000 Sq.ft

## Best-in-class Instrumentation and Technology



LCMS, LCMS-MS, HPLC, NMR Spectrophotometer, SFC, HTS

## Our People



Total Employees	~1700
Scientific Domain	~1500
Functional Domain	~250
PhDs	~200



# Unlocking true potential- Our People

- Practices to support volume and value hiring in short lead time
- Strong bench of associates to deploy as per clients' needs



- Periodic goal setting, review based on metrics
- Regulatory, QA & safety practices alignment during induction

- Career management aligned with Tower Watson job architecture
- L&D sessions- Soft skills, technical and management skills

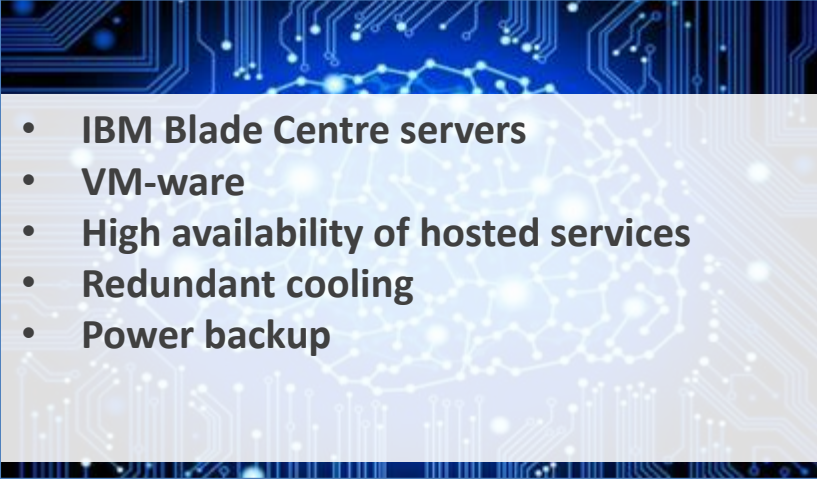
- Employee connect programs with CEO /BU Heads/ Sr. Management
- Prism- Sports, events and celebrations

- Strong pool of scientists: **200+** Doctorates
- Over **20,342** hours of soft skills training in FY15
- **107** soft skill & behavioural training sessions conducted in FY15
- Training program consistently rated **4.2/5**
- **Best L&D practices award** by world HRD congress in 2013, 2014 & 2015

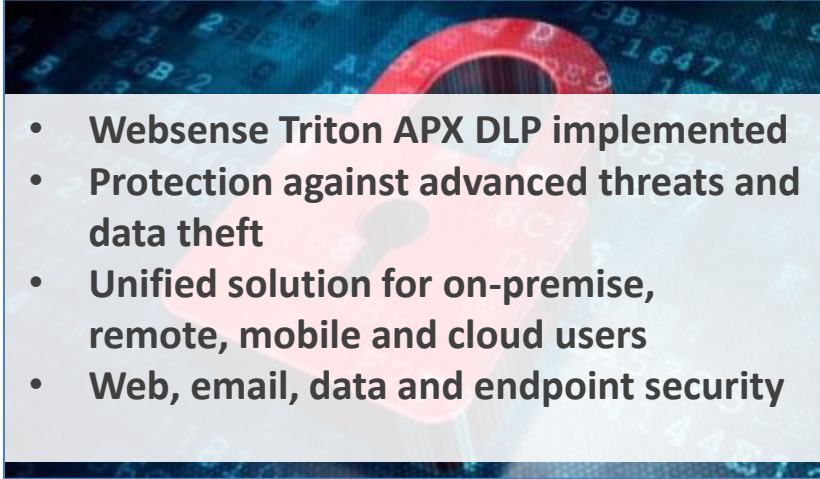


# IT Infrastructure: User Protection- Anywhere, Anytime

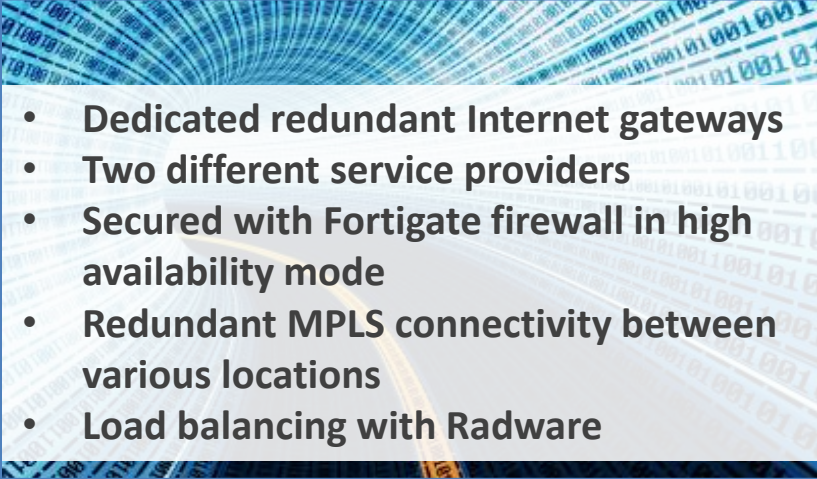
## Data Center

- 
- A background image for the Data Center section featuring a blue and white circuit board pattern with glowing nodes and lines, suggesting a network or data center environment.
- IBM Blade Centre servers
  - VM-ware
  - High availability of hosted services
  - Redundant cooling
  - Power backup

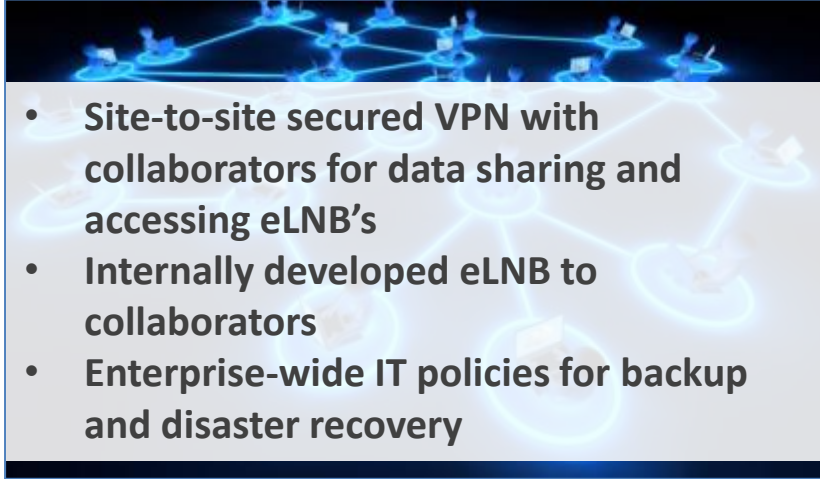
## IT Security

- 
- A background image for the IT Security section featuring a dark blue background with glowing binary code (0s and 1s) and a prominent red padlock icon, symbolizing security.
- Websense Triton APX DLP implemented
  - Protection against advanced threats and data theft
  - Unified solution for on-premise, remote, mobile and cloud users
  - Web, email, data and endpoint security

## Enterprise Connectivity

- 
- A background image for the Enterprise Connectivity section featuring a blue and white network diagram with glowing nodes and lines, overlaid on a background of binary code.
- Dedicated redundant Internet gateways
  - Two different service providers
  - Secured with Fortigate firewall in high availability mode
  - Redundant MPLS connectivity between various locations
  - Load balancing with Radware

## Collaboration

- 
- A background image for the Collaboration section featuring a blue and white network diagram with glowing nodes and lines, overlaid on a background of binary code.
- Site-to-site secured VPN with collaborators for data sharing and accessing eLNB's
  - Internally developed eLNB to collaborators
  - Enterprise-wide IT policies for backup and disaster recovery

# SHE- An Integral part of our Business

## Our Safety policy:

- Promoting awareness on safety, health and environment
- Complying with all the applicable Safety, Health & Environment legislations and regulations
- Operating facilities which minimize adverse impact on environment
- Maintaining safe work place conditions

## SAFETY AND COMPLIANCE FIRST BUSINESS LATER



- Safety management process
- Emergency preparedness
- Permit to work systems
- Accident/Incident reporting system
- Personal protective equipment



- On-site Medical officer
- Occupational health centre
- Ambulance & nursing
- Periodic medical examination
- Medical insurance



- Waste management
- ETP- Zero liquid discharge facility
- Treatment and recycling of domestic water
- Green-belt maintenance

# GVK Beyond Business

## HEALTHCARE GVK EMRI



India's largest emergency response services. Covers over 750 million people across India

## ENVIRONMENT & SUSTAINABILITY



Energy conservation, water management and efforts to minimize ecological impact

## COMMUNITY DEVELOPMENT



Education, Health and hygiene, Empowerment, Entrepreneurship development

## ART, CULTURE AND SPORTS



3 km Art Wall, at the new T2 terminal, Mumbai. Supports and endorses excellence in sports

## GVK BIO- Focus Areas

### EDUCATION



### HEALTHCARE



### ENVIRONMENT






### EMPOWERMENT



### SPORTS

# Global Footprint



-  **Corporate Office:** Hyderabad, India
-  **Operations:** Hyderabad, Bengaluru, California
-  **International Offices:** Boston (U.S.A), Amsterdam (Netherlands)
-  **Ground Presence:** Maryland, Boston, Albany, San Francisco, Netherlands, Osaka



## REACH US

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