GVK BIO
Accelerating Research

# Analytical Development Services

# GVK BIO – A Group Company Of GVK Conglomerate

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Accelerating Research

**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

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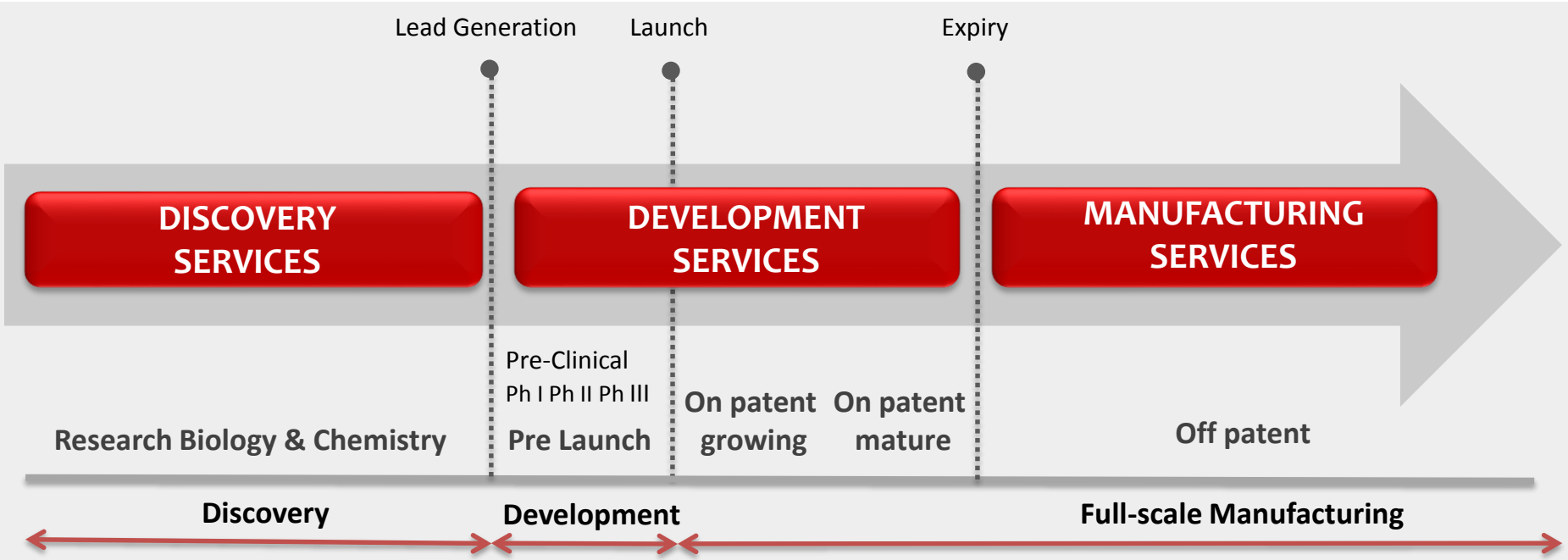
- **Asia's leading Integrated Drug Discovery Research, Development and Manufacturing organization, established in 2001**
- **A large pool of scientific talent, over 1500 scientists and 200 PhDs**
- **400+ clients globally**
- **State-of-the-art infrastructure spread across 55 acres of land**



# Resources

**> 1,200,000 Sq. ft. of lab & manufacturing infrastructure spread across 55 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 (Bengaluru)
100,000 Sq.ft

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

Large Molecule R&D Services (California)
20,000 Sq.ft

**Infrastructure under development**

Manufacturing Services (Vizag)
170,000 Sq.ft

## Best-in-class Instrumentation and Technology

## Our People

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

# 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**

**High Potent APIs**

**Analytical Services**

**Formulation R&D Services**

**Regulatory Support**

## MANUFACTURING

**Contract Manufacturing**

**Process Validations and DMF Filings**

**Commercial APIs and Intermediates**

# Analytical Services Overview

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Discovery → Medchem → Preclinical → Drug Candidate → IND → Phase I to III

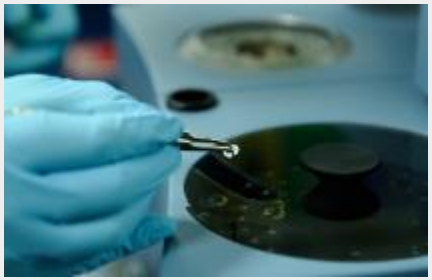
Quality control and release testing

Analytical method development and validation

Stability & photo stability testing, storage and management

Impurity profiling and trace metal analysis

Microbiology



Physicochemical characterization

Dissolution profile

Extractable/ Leachable analysis

# Quality Control and Release Testing

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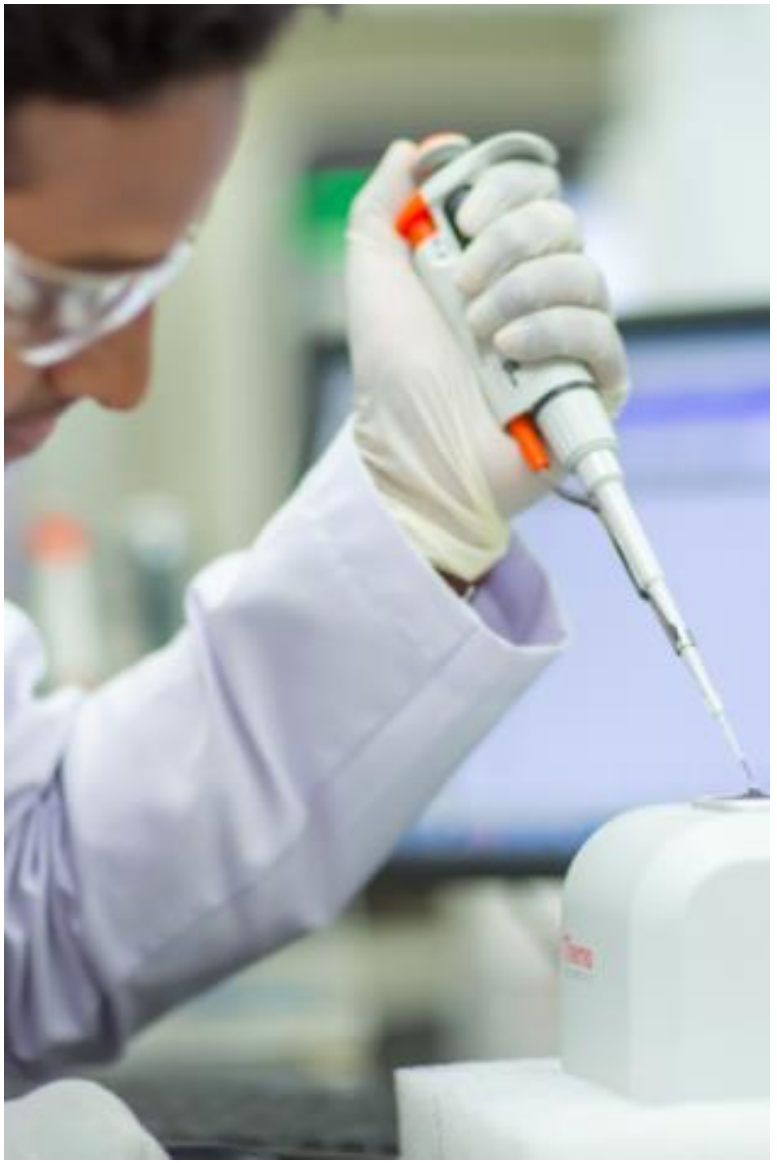
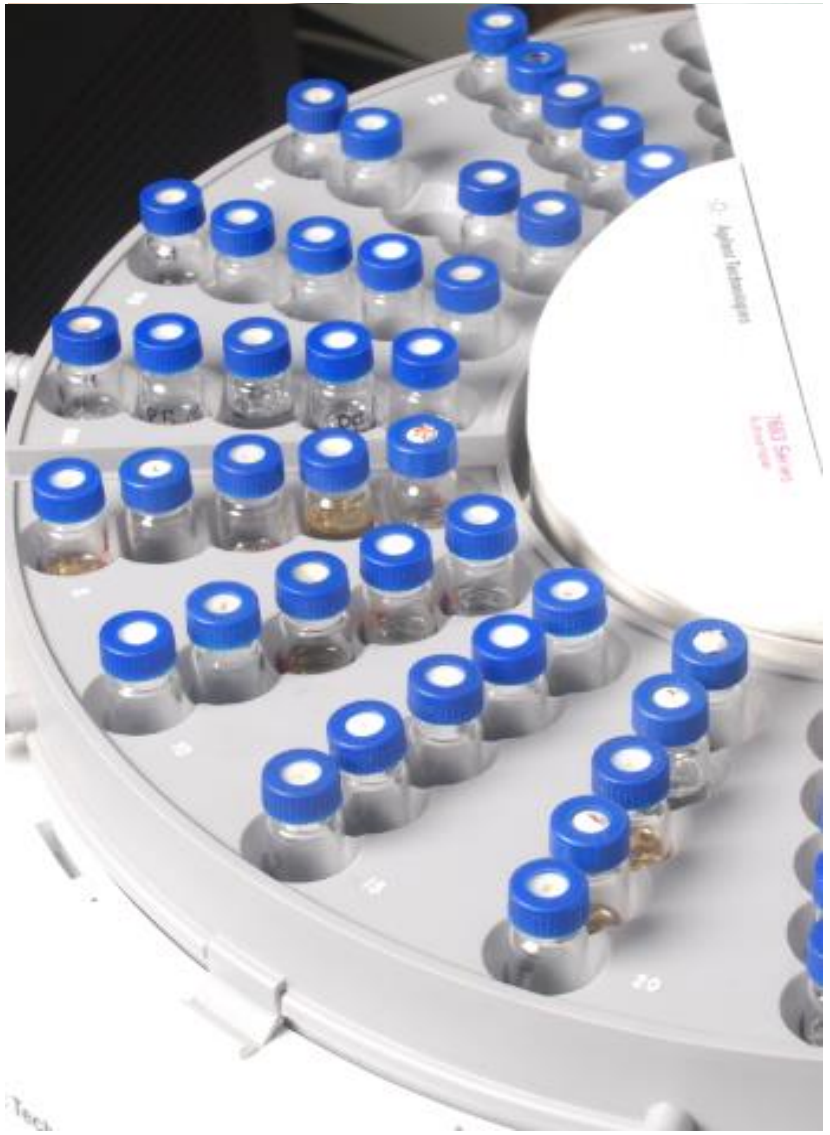
- Chromatographic analysis (HPLC with UV, PDA, ELSD, RI and GC with FID, TCD)
- Spectroscopic analysis (UV, MS, IR)
- Physical and physicochemical analysis (pH, Wet analysis, Particle size, TGA, DSC, CHNS)
- Residual solvents and organic volatile impurities
- Analytical testing for various dosage forms (Solid orals, syrups, patches, creams, gels etc.)
- Dissolution, hardness & friability for solid orals
- Trace metal analysis (ICP-MS)
- Morphology screening (XRD)
- Genotoxic impurities determination



# Analytical Method Development & Validation

- Wide range of chromatography techniques (HPLC, UPLC, GC, ICP and LC)
- Detection technologies (UV, MS, ELSD, RI, FID, PDA etc.)
- Stability-indicating assay and/or related substances methods for DS & DP
- Dissolution testing, organic volatile impurities
- Preservatives and antioxidants
- Enantiomeric separation
- Cleaning validation
- Dose verification for GLP studies



# Stability Studies

- cGMP registration stability programs
- Consultancy on design, storage and management
- Development and validation of stability indicating methods including dissolution testing
- Validated monitoring system, 21 CFR part 11 compliant
- Walk-in and backup reach-in chambers
- Comprehensive documentation

**All ICH + specific conditions**

- Long-term stability studies
- Short term, accelerated studies
- Follow-up stabilities
- Photo stability testing

| Temperature | Humidity |
|---|---|
| 25°C ± 2°C | 60% RH ± 5% RH |
| 30°C ± 2°C | 65% RH ± 5% RH |
| 30°C ± 2°C | 75% RH ± 5% RH |
| 40°C ± 2°C | 75% RH ± 5% RH |
| 5°C ± 3°C | No Humidity |

**Comprehensive stability services virtually for every dosage form at various stages of drug product lifecycle**

# Impurity Profiling and Trace Metal Analysis

- Genotoxic impurities method development and validation by LC-MS and GC-MS
- Elemental impurities method development and validation by ICP-MS for Class 1, 2A and 2B as per regulatory requirement
- Content method development and validation by LC-MS and GC-MS
- Method development and validation of organic volatile impurities as per ICH guidelines
- Method development and validation for non-chromophoric compounds by using RI and ELSD detectors

# Microbiology

- Microbial limits tests
- Microbial contaminant identification
- Microbiological assessment of antibiotics
- Bacterial endotoxins
- Environmental monitoring

# Physicochemical Characterization

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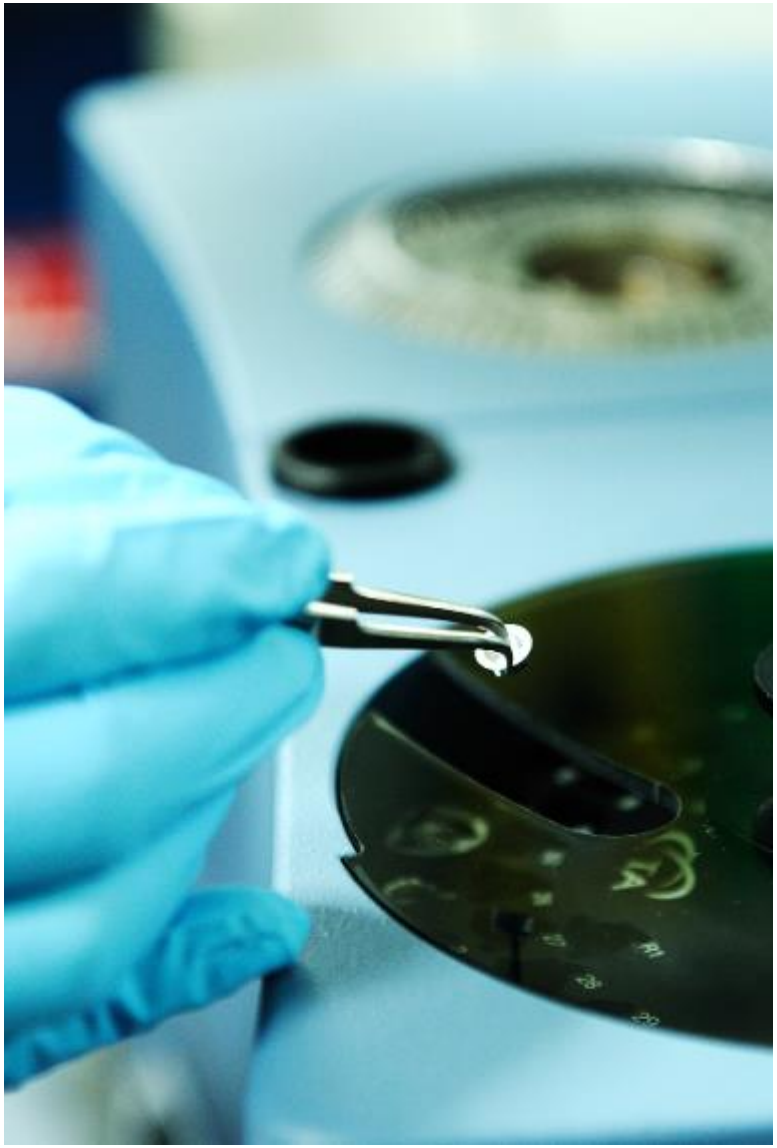
## Reference standard characterization

- Materials characterization
- Thermal analyses
- Particle-size characterization
- Spectroscopy (FTIR, LC-MS, GC-MS, UV, etc.)
- Salt form screening and selection
- Polymorph screening

## Structural Chemistry Services

- Impurity and degradation product identification and structural elucidation
- Characterization of API, product, reference standard and other pharmaceutical ingredients
- Trace element analyses and quantitation by ICP-MS
- Accurate mass determination for small molecules



# Dissolution and Formulation Analysis

- Dissolution -solid oral dosage form (USP-1 and USP-2)
- Hardness
- Friability
- Content of uniformity
- Uniformity of mass
- DDU (Delivered Dose Uniformity) and MDD (Mean Delivered Dose) for inhalers
- Impurity identification and determination
- Chromatographic analysis
- Spectrophotometric analysis

# Extractables & Leachables

- Controlled extraction studies utilizing HPLC, LC-MS, GC-MS, GC-HS-MS and ICP-MS with data interpretation and extractable screening for both organic compounds and inorganic elements
- Determination of AET (Analytical Evaluation Threshold) and SCT (Safety Concern Threshold)
- Development and validation of analytical methods for potential leachable identification and quantification
- Material qualification for polynuclear aromatic hydrocarbons (PAH), N-nitrosamines and other compounds of toxicological concerns
- Leachables monitoring during shelf life and routine extractable testing

- Bags, vials and prefilled syringes for injectable
- Transdermal patches
- Stoppers, vials, nasal spray pumps, labels, adhesives, inks, tubing, resin, film, caps, foil, gasket, valves and disposable materials used in OINDPs

# Analytical Infrastructure (cGMP area)

- High Performance Liquid Chromatography
- Gas Chromatography coupled with Mass Spectrometry
- Gas Chromatography coupled with Head Space
- Liquid Chromatography coupled with Mass Spectrometry
- Inductively coupled plasma mass spectroscopy
- Microwave digestion system
- Particle Size Analyzer
- X-Ray Diffractometer
- Differential Scanning Calorimeter
- Thermo Gravimetric Analyzer
- CHNS
- Dissolution Apparatus-14x
- Dissolution Apparatus-8x
- Tablet Force tester
- Friability Apparatus
- Walk in Stability chamber
- Reach-in Stability chamber
- Photo Stability chamber
- Cold chamber
- KF Titrator
- Auto Titrator
- Fourier Transformer Infrared Spectroscopy
- Hot Air Oven
- Muffle furnace
- Analytical Balance
- Micro Balance

# cGMP Analytical Facility

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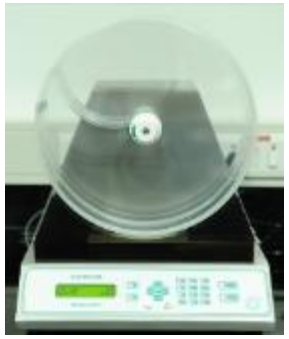


# Analytical Capabilities (Non-GMP area)

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## SFC Parallel screening technique with 5 detectors in parallel

*FASTER SCREENING: 5 FOLD SPEED*

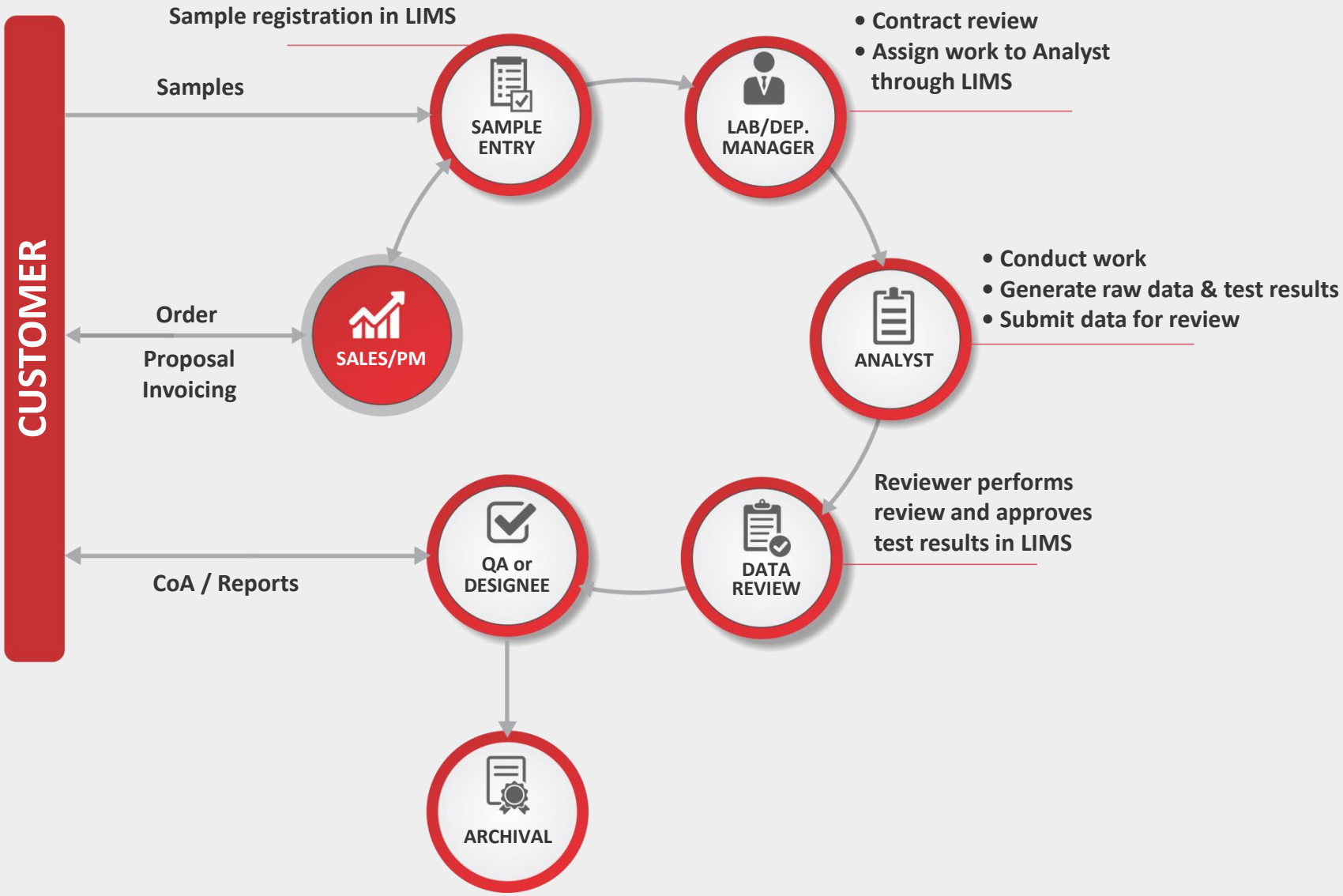
- **Multiple column selection valve enables screening with different stationary phases in parallel & SFC analytical method station for serial method scouting**
- **Two method stations and one X5 Parallel screening instrument are available for method screening activity**
- **Normal phase method screening for chiral & achiral separations**
- **ELSD chiral screening in normal phase method for non-chromophores**

## SFC -Purification (4-Prep Instruments)

- **Variety of chiral stationary columns (12-phases):** Maximum output/day- 120 g
- **SFC purifications up to 3 Kg**

## NMR - Bruker & Varian 400 & 500 MHz instruments

# Samples and Documents Workflow



# Quality Management System

- **Based on GxP principles**
- **Incorporates additional certifications on local levels:**

  Local FDA, ISO 17025*
- **Under supervision of Corporate Quality Assurance**
  - Routine Process Audits & Internal Quality checks
  - Regular quality system training to Staff
- **Implementation of quality systems in accordance with cGMP, GLP, ISO 17025**
- **Empower-3 (Waters) network server for chromatography data management**
- **Total data management through validated LIMS (LABVANTAGE) with a dedicated server**


* Accreditation in process

# Why GVK BIO

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High quality services, short response time and reliable delivery.
***Speed to market***

Consultative Approach towards problem solving.
***Build synergies***

Successful track record in handling large FTE programs and addressing challenging sponsor needs.
***Expertise that delights***

Experience of working with MNCs, including 16 of the top 20 Pharmaceutical companies.
***Trusted by leaders***

Dedicated Project managers and individualized customer service.
***Personalization and commitment***

Customized outsourcing models and minimal contractual notice periods.
***Tailored to your needs***

Financial ability to quickly scale-up infrastructure and skilled workforce in line with project requirements.
***Flexibility and competency***

Powered by LIMS, Empower 3, Robust Confidentiality/IP protection and SHE.
***Transparency and quality assurance***

# Global Footprint

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

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# REACH US


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