



Process Development & Manufacturing Partner

Small molecule drug substances | Regulatory starting materials (RSMs)



ICH Q7 compliant GMP manufacturing plant to produce kilo to MT scale



Expertise in complex chemistry optimization and scale-up



Process development and manufacturing of specialty chemicals



Analytical development and stability indicative studies

About Us

Eurofins CDMO India is a leading partner within the Eurofins CDMO network, bringing over 15 years of proven expertise in GMP manufacturing and process development.

We specialize in the manufacturing of Regulatory Starting Materials (RSMs) and drug substances for FIH Phase 1 and Phase 2 clinical studies, along with analytical method development and process optimization.

Our reputation is built on delivering global quality standards with a strong emphasis on efficiency, timely execution, and cost-effective solutions. We proudly support a diverse clientele—from emerging biotech innovators to multinational pharmaceutical and specialty chemical companies.

Why Partner With Us?



Flexible manufacturing with multiple production lines



Storage capabilities for varied temperature and hazard classes



ISO Class 8 certified cleanroom facilities



Comprehensive safety and regulatory compliance systems



Robust supply chain and logistics support



Strong commitment to IP protection and confidentiality



Manufacturing Capabilities

- Adaptive manufacturing suits
- Lab to kilo lab scale-up for preclinical studies
- cGMP and non-GMP manufacturing of RSMs/NCEs
- Seamless tech transfer from R&D to manufacturing
- Quality and On Time, In Full (QOTIF) delivery
- Strategic outsourcing & backward integration
- Zero Liquid Discharge (ZLD) effluent plant with mechanical vapour recompression
- Reactors from 20 L to 4000 L (SS, GL, all-glass)
- Cleanrooms for final product isolation
- Powder handling
- Large-scale chromatography

Description	No. of Reactors	Volume
3 floors, 3 lines of finished API facility with ISO class-8	32	50 kL
Intermediate area	15	0.63 kL – 4 kL
Pilot plant	4	0.10 kL – 0.25 kL
Hydrogenators	3	0.25 kL – 2 kL
Corrosive reactions	2	0.63 kL – 1.6 kL
Cryogenic reactor	1	0.5 kL
Clean Rooms	7	3 kL – 4 kL

Equipment

Reactors, Centrifuges, Nutsche Filters, ANFDs, Vacuum Dryers, Lyophilizer, Sparkler Filters, Multimill, Sifter, Blender, Micronizer

Utilities

Vacuum, thermic fluid, chilled water, brine, liquid Nitrogen (–78°C to +200°C)

Process Development

Services

- Route scouting & selection
- Phase appropriate process development
- Salt screening, crystallization, polymorph studies
- Qbd/DoE-based process development
- Analytical method development, verification and validation
- Impurity identification and characterisation
- Stability studies
- Process safety studies using tools like μ RC, ARC, DSC, etc.
- HPAPI process development
- Chemical synthesis and scale-up under cGMP and non-GMP
- Automated chromatography
- Kilo lab facility

Infrastructure

- Mini-block parallel synthesis system/Radleys
- ARRST
- Jacketed reactors
- Biotage purification systems
- Lyophilisers
- Spray drying

Analytical Development

Services

- Method development for RSMs, intermediates, APIs and GTIs
- ICH compliant forced degradation studies
- Physical and chemical characterisation
- Standard test procedures
- Impurities: isolation / characterisation / profiling for RSM
- Reports: cutoff/carryover studies; holding studies
- Reference standards qualification
- Analytical method qualification/validation reports
- Solid state characterisation stability studies as per ICH guidelines

Infrastructure

- HPLC, UPLC, GC-MS, GC-HS, Ion Chromatography
- ELSD, CAD, PDA
- ICP-MS
- UV-Vis, FTIR, 400 MHz NMR (multi-nuclear probe)
- DSC, pXRD, Particle Size Analyzer
- Automated Prep-HPLC with PDA & ELSD
- ICH compliant stability chambers

Supply Chain and Logistics

- Sourcing strategy with multi-geography vendors
- Domestic vendor development for key raw materials (KRM) and intermediates
- Dual-sourcing strategy for commercial supply
- Site audit-based vendor qualification
- Logistic partners: DHL, FedEx (ambient); Marken, World Courier (cold chain)
- Global shipping experience (USA, Europe, Japan) with custom clearance support

Warehouse Facility

- Dedicated storage for raw materials, packing materials, rejected materials and finished goods
- Walk-in coolers and deep freezers to store material at 2 to 8°C and – 20°C
- Dedicated dispensing area for materials
- Separate area for storing hazardous materials and activated charcoals



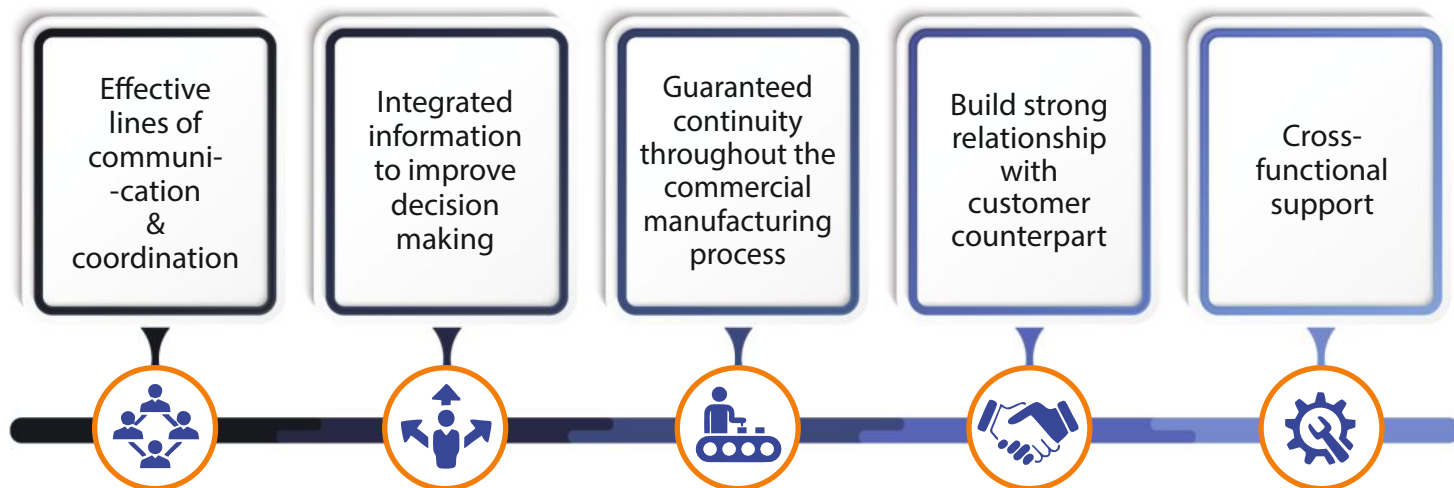
Safety Management

- Fire hydrant systems (automated pumps, 29 hydrants, 13 hose reels, 2 brigade inlets)
- Smoke detectors (200+ points), fire alarms, extinguishers, PPE
- Zero liquid discharge facility
- HAZOP, risk assessment during scale-up
- Pollution control and waste management

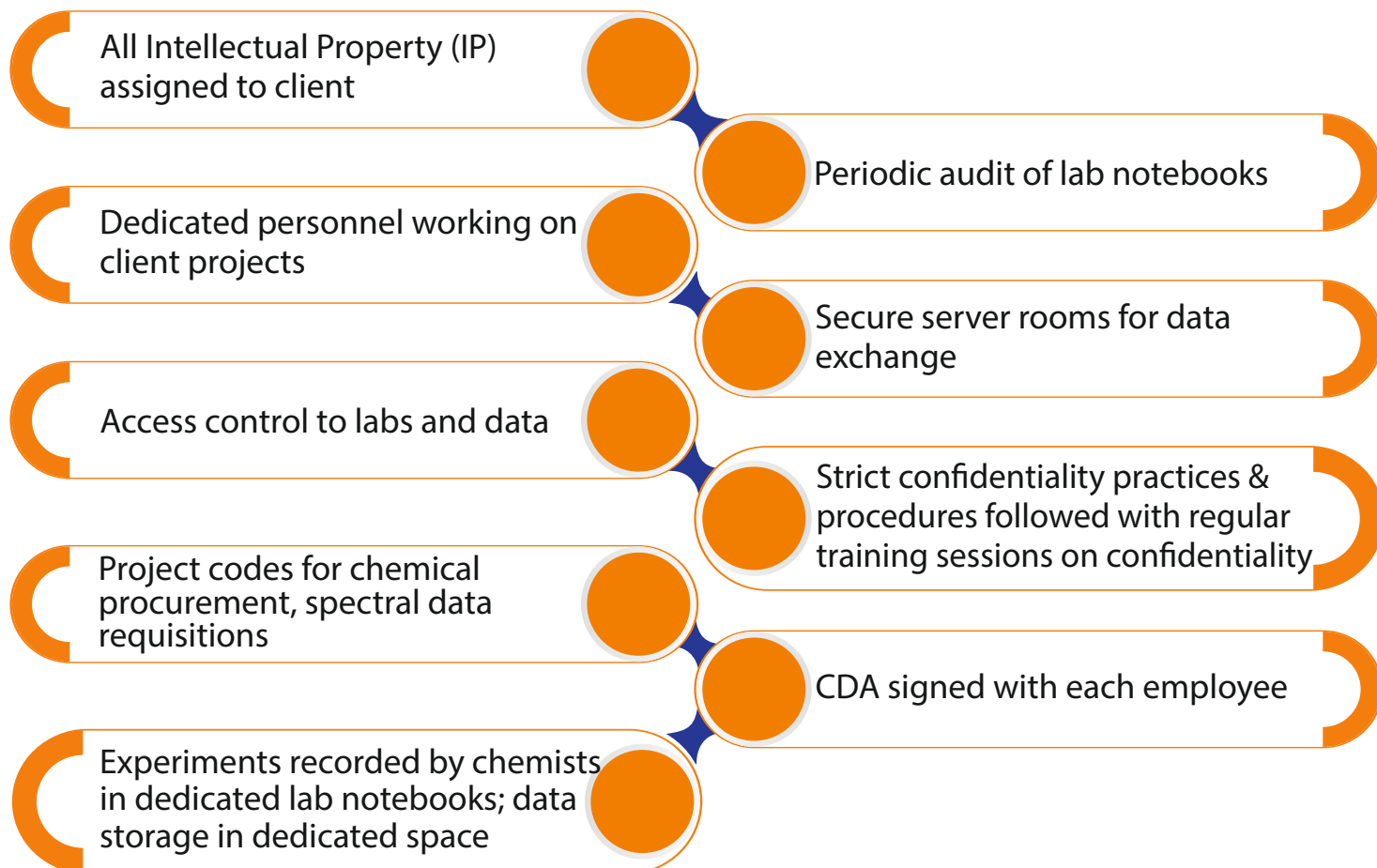


Project Management

Dedicated project manager handling all queries & ensuring smooth operations



IP and Confidentiality



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Scan to contact us :

