eurofins | CDMO

Eurofins Advinus

Well Equipped To Accelerate Your Drug Development

- Highly Qualified & Experienced Scientific Team
- Experience In Performing Complex Chemistry Reactions
- Manufacturing Plant To Produce Drug Substance From Kilo To MT Scale
- CMC Regulatory Support For Drug Substance

About Eurofins CDMO India:

With over 15 years of experience, Eurofins CDMO India offers comprehensive Chemistry, Manufacturing & Controls (CMC) services to help clients with drug substance development and manufacturing. We are known for our reliable and high-quality services in route scouting, process development, analytical method development and manufacturing of drug substance for tox, clinical studies and commercial use. We offer global quality at competitive price with optimal time and resource management. Eurofins CDMO India's client base ranges from small biotech to big pharma and specialty chemical companies.

- Well Established Supply Chain And Logistics
- Different Storage Conditions
- Multiple Production Lines
- Class 8 Clean Rooms
- Safety Management
- Regulatory & Quality
- Project Management
- IP Protection & Confidentiality

Manufacturing Facility

Eurofins CDMO India

Comprehensive CDMO Services

Process Chemistry

- Route selection
- Fit-for-purpose process development and optimization
- QbD based process development
- Salt screening and polymorph evaluation
- Stability studies
- Process safety studies

Analytical Chemistry

- Standalone or integrated with CMC services
- Method development and validation
- Method verification and transfer
- Forced degradation and stability testing (as per ICH)
- Impurity isolation, identification (characterization) and profiling
- Isolation and characterization

Manufacturing Capabilities

- Rapid piloting and scale-up
- Non-cGMP and cGMP manufacturing
- Supply of RSMs (Regulatory Starting Materials)
- NCE/API manufacturing
- Process validation
- Stability studies

Formulation Development Services

- Preformulation:
  - Solubility, Solubilization, pH solution stability, forced degradation, API characterizations
- Early formulations for preclinical dosing:
  - Formulation development including analytical support
- Stability study of drug product:
  - Multiple Storage Conditions, Photo stability studies
- Formulation Development and Scale up/ Technology transfer for Clinical trials:
  - Oral dosage forms like uncoated and coated tablets, capsules, Modified Release formulations etc.
  - Parenteral dosage forms like solutions, lyophilized powders for injection, suspensions and Modified Release formulations etc.
  - Development based on QbD principles

Manufacturing Production Lines

Description	No. of Reactors	Volume
3 floors, 2 lines of finished API facility with ISO class - 8	28	50 kL
Intermediate area	15	0.63 kL – 4 kL
Pilot plant	3	0.16 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	4	3 kL – 4 kL
Major process equipment with supporting equipment	Reactors, Centrifuge, Nutsche filter, ANFD, Rotocon vacuum dryers, Lyophilizer, Sparkler filters, Multimill, Sifter, Blender, Micronizer	
Utility capabilities	Vacuum, thermic fluid heater, chilled water, chilled brine, liquid n2 -78^{0}c to +200^{0}c	

Supply Chain and Logistics

- Procurement strategy with multi-geography vendors for RMS & intermediates
- Development of domestic vendors for KRMs & intermediates to mitigate any supply risk
- Long-term supply agreements with minimum two vendors for commercial projects
- Well established vendor qualification methodologies including site visit/audit for late phase compounds
- Tie-up with major logistics providers like DHL & FedEx for ambient temperature shipments and world courier & marken for cold chain shipments (-20^{0}c)
- Tie up with freight clearing agents for smooth custom clearance and shipments
- Experience in handling shipments to usa, europe & japan

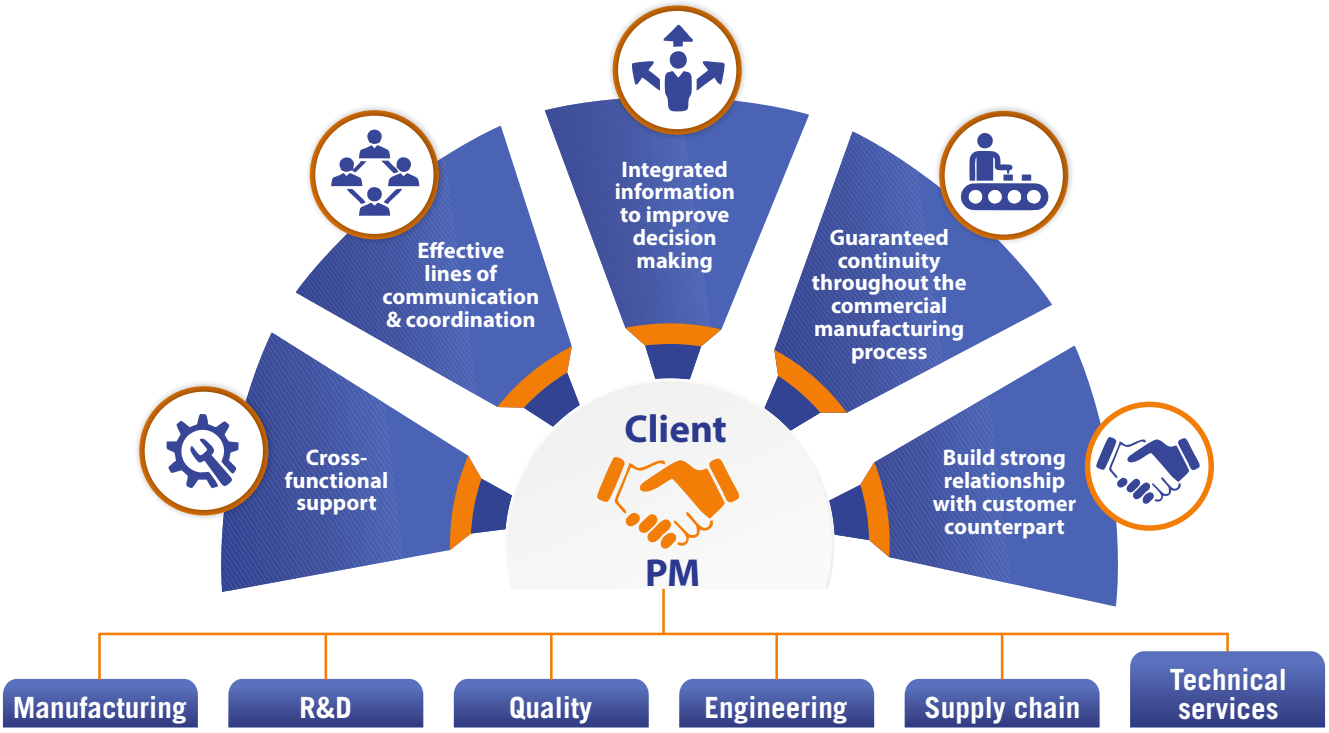
Warehouse Facility

- Dedicated storage for raw materials, packing materials, rejected materials and finished goods
- Walk-in coolers and deep freezes to store materials at 2 to 8^{0}C and -20^{0}C
- Dedicated dispensing area for materials
- Separate area for storing hazardous materials and activated charcoals

Safety Management

- Fire hydrant system consists of:
  - Automated fire water pump
  - 29 single fire hydrants
  - 13 hose reel drums
  - 2 fire brigade inlets
- Zero liquid discharge facility
- Waste management including disposal system
- HAZOP, risk assessment during scale-up
- Pollution control monitoring systems
- The entire facility is provided with fire alarm system with smoke detectors (200 locations)
- Appropriate fire extinguishers and PPEs
- CCTV cameras in appropriate locations

Project Management



Dedicated Project Manager handling all queries & ensuring smooth operations

IP and Confidentiality

- All Intellectual Property (IP) assigned to client
- Dedicated personnel working on client projects
- Access control to labs and data
- Project codes for chemical procurement, spectral data requisitions
- Experiments recorded by chemists in dedicated lab notebooks; data storage in dedicated space
- Periodic audit of lab notebooks
- Secure server rooms for data exchange
- Strict confidentiality practices and procedures followed – Regular training sessions on confidentiality
- CDA signed with each employee

Eurofins Advinus Biopharma Services India Pvt. Ltd.

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