

Exclusive Synthesis- Intermediates & APIs

Project Management

Every project of customer is handled with due care by a dedicated Project Manager to ensure:

- One Point of Contact, for customers, who coordinates internally with various functions
- Identifies risks and their mitigation plans to ensure timely implementation of Projects
- Communicates periodically with customers on project progression, documentation etc. on a mutually agreed reporting format and timelines. As and when required, Project Manager brings cross-functional team on board to have interaction with customers
- Jubilant has already implemented Enterprise Project Management (EPM) in order to track the deliverables of various functions by top level management
- **Enterprise Project Management (EPM) Web Based Tool:** It identifies, records, shares, tracks, resolves and communicates all issues pertaining to the project.
- **Project Management Professional Certification:** For correct application of Tools and Techniques, all Project Managers and key functional contributors in CRAMS projects have to obtain 35 Hrs Professional Development Units (PDU's) by taking a 5 day session on PMP certification program conducted by PMI (Project Management Institute) and clearing the examination.

Customer's Profile and Project Pipeline

- We work with large innovator Pharma, small and mid sized Biotech & Crop Science Companies.
- Jubilant has in-market commercial projects where it has signed long-term agreement with customers
- Currently working on several projects at commercialised scale on long term contract manufacturing model
- We have several projects in Phase-I, Phase-II and Phase III, where we have good chance for them to reach the launch stage

Jubilant Value Proposition

- Jubilant has over 30 years of experience in developing and manufacturing robust, cost effective, environment friendly chemical processes
- Expertise of Speedy and Seamless integration from lab scale development to scale-up technology transfer to plant design (through our inhouse basic and detail engineering team) to fastest fabrication and execution to commercial product supply
- Strict Compliance to global IPR standards
- Implemented Business excellence tools like Six-Sigma, TPM, SCOR (Supply Chain Operative Reference) which are features of continuous improvements in system and process
- Vast experience and good track record of working with global life science customers with long-term relationship

Jubilant has expertise in developing and manufacturing complex chemical processes. Using this expertise, Jubilant provides Process Development and Manufacturing Services to Life Sciences Industry for Intermediates and APIs.

Business Offerings

Research & Developmental Services (Intermediates & APIs)

- Routes design, process development and process optimisation for early phase clinical projects in pre-clinical/phase I to III
- Cost effective process development and optimisation for in-market and launched products
- Analytical protocol development with complete dossier preparation on demand

These processes are developed with emphasis on being environment friendly, scalability, ease of operation and process robustness. Jubilant often makes use of statistical Design of Experiments (DOE) for developing these processes.

Custom Manufacturing (Intermediates & APIs)

The Company takes up manufacturing projects of developmental products in Clinical phase as well as of in-market products from a few Kilograms to several Metric ton quantities on a regular basis.

The business handles projects having:

- **Process received from the customer:** Through process familiarisation, contractual agreement, complete technology transfer, commercial manufacturing
- **Process to be developed:** Through route selection, sample preparation, sample approval, process optimisation, contractual agreement, pilot trial, commercial manufacturing



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Technology Platforms

All Core technologies are being used at large scale productions and have global competitiveness. The Classical technologies are also being experienced at various scale of manufacturing.

Core Technology Platforms

- Aromatisation
- Vapour Phase Reaction (upto 450°C)
- Chichibabin Reaction
- Stereo Selective Hydrogenation
- High Pressure Hydrogenation, (upto 58 kg pressure and 270°C in 6KL reactor)
- Butyl Li Rxn (upto -80°C)
- Alkylation / Methylation
- Oxidation
- Quaternisation
- Grignard Reaction
- Phosphate Esters / POCl_3 handling
- Sodamide / Sodium methoxide Reaction
- Sandmeyer Reaction
- Fermentation
- Halogenations (Including Photo chlorination)
- Ammoxidation
- Beckmann Rearrangement
- Mannich Reaction

Classical Technologies

- Cyclocondensation
- Hoffmann Bromide
- Alkali metal Cyanide
- Fluorine exchange
- TMSCN
- Dehalogenation
- Nitration
- Reduction
- Dehydration
- Claisen condensation
- Transesterification
- Halogenation
- Balz-Schiemann
- Diazotisation
- Nitrations
- Hantzsch Synthesis
- Amination
- Dealkylation
- Ethoxylation
- Many more...

Research & Development

- Exclusive Synthesis has R&D facilities at Noida and Gajraula (near Delhi) for Intermediate and APIs
- Fully Equipped analytical laboratory with advance equipment including NMR, XRD, Reaction Calorimeter, LC-MS, Prep HPLC, Particle size analyzer, Optical microscope, Stability Chambers, Polarimeter, IR, DSC, TSC etc.
- All projects in R&D are properly coded and distributed to maintain strict confidentiality

Manufacturing Facilities

Pilot Plants

We have state-of-art Kilo-Lab and Pilot plants both at Gajraula (Near Delhi) for Non-Regulatory steps synthesis and at Nanjangud (Near Bengaluru) for Regulatory steps synthesis. Pilot plant at both locations are cGMP compliant.

- Reactors ranging from 20L to 630L (Including Glass assemblies and Cryogenic reactors, Autoclaves operating at 58 Kg/cm² and 280°C)
- Equipments like Centrifuges (Including SS, Rubber lined, Halar Coated), Dryers, Columns, High Vacuum Systems
- All required utilities to operate at very high (450°C) and very low (-80°C) temperatures

Commercial Plants

We have cGMP compliant commercial plants at Gajraula (Near Delhi) for Non-Regulatory steps synthesis and at Nanjangud (Near Bengaluru) for regulatory intermediates and APIs. Our Nanjangud facility is USFDA approved.

- At Nanjangud Facility we have 107 reactors (Including MSGLR, SS, Hastelloy and Cryogenic) ranging from 1 KL to 12 KL having reactor volume of 650 KL along with the Autoclaves operating at 58 kg/cm² & 280°C, Bromination and Fluorination facilities
- At Gajraula facility we have 100 reactors (Including MSGLR, SS, Hastelloy and Cryogenic) ranging from (1KL to 12 KL) having reactor volume of 600 KL, along with the Autoclaves operating at 58 Kg/cm² & 280°C, Bromination and Fluorination facilities
- Equipments like: Dryers, Centrifuges, High Vacuum System, Highly Efficient Distillation Columns with structured packing of 30 meters packed height, Solvent Recovery Plants

Continuous Improvement Through Business Excellence Tools

Our team uses various business excellence tools to provide continuous improvements in process as well as cost.

- **DFSS (Design For Six Sigma)** – Provides the most optimum & cost efficient process to scale-up via various designs of experiment.
- **Lean Six Sigma** – Used effectively to cut down the cycle time and removing waste from the process.
- **TPM** – Used effectively to maximize capacity utilization in short and long run.
- **SCOR** – To integrate the well known concept of business process re-engineering, benchmarking and process measurement into a cross-functional framework