

CONTRACT DEVELOPMENT
AND MANUFACTURING
(CDMO)





Jubilant's CDMO

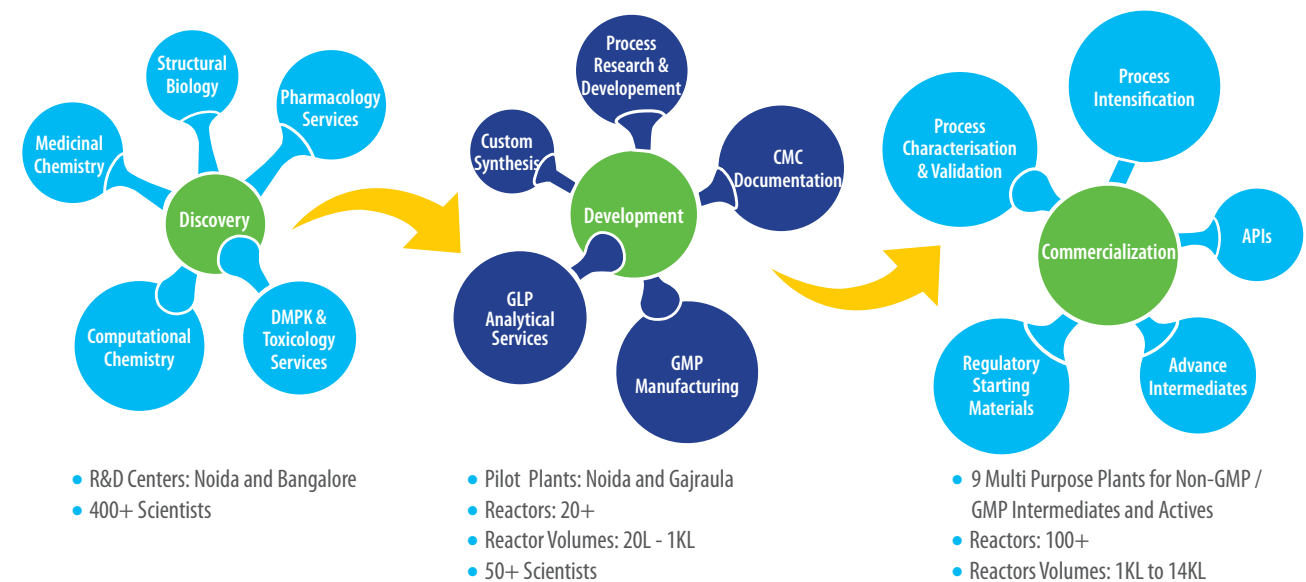
Jubilant Life Sciences with its strong Medicinal, Synthetic, Organic Chemistry and Manufacturing Capabilities has established itself as an important partner resource for Contract Development and Manufacturing (CDMO) services. We strive to offer solutions across the entire Pharmaceutical Value Chain from grams to multimetric tons of custom small molecules as desired by customers.

What is Jubilant CDMO?

Jubilant LifeSciences' CDMO acts as an outsourcing partner for many Life Science innovators and has adopted a new encompassing concept for its range of services.

A number of additional strengths now make up the DNA of this integrated Pharma and Life Sciences Company with a lot of opportunity for innovator partners to collaborate through all stages of a product life cycle.

Jubilant's CDMO: Integrated Service Provider

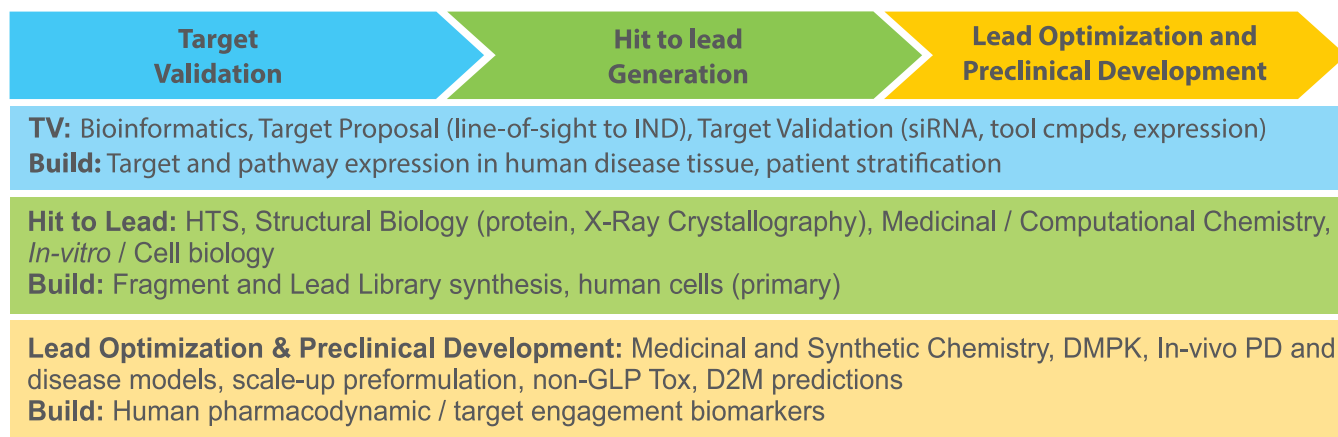


Project Management for each phase enabling transfer to the next enabled by a customer centric approach.

DRUG DISCOVERY & CDMO SERVICES

Jubilant provides Discovery, MedChem, Process R&D, Scale-Up and Manufacturing Services to Pharma and Life Sciences Innovators for RSM's, Intermediates and APIs.

Discovery Services



- Target Identification/ Target Validation to Lead Optimization/ Preclinical candidate, for multiple therapeutic areas viz; Oncology, Metabolic Disorders, CNS, Pain, Inflammation, Fibrosis and Respiratory diseases.
- Functional services comprising of computational chemistry/ molecular modelling, medicinal chemistry, synthetic chemistry, scale-up (Non-GMP & GMP), structural biology, ADME-PK, in-vitro and in-vivo biology and IND enabling GLP toxicology.

Synthetic Chemistry Services

- Route design, process development and process optimization from Phase I to III
- Process improvement for launched products, dosage as well as actives.
- Regulatory and Analytical support required for CMC section of registrations.

These processes are developed with criteria on environmental impact, scalability, ease of operation and robustness. Jubilant applies Design For Six Sigma (DFSS) and Design of Experiments (DOE) expertise to develop these processes.

FACILITIES

- Jubilant has R&D facilities at Noida, Bangalore, Gajraula (near Delhi) with scale from mg to ton levels.
- Fully equipped analytical laboratory with NMR, XRD, Reaction Calorimeter, LCMS, Prep HPLC, MS directed Prep HPLC, Rapid Fire, SFC, HRMS, particle size analyzer, Optical microscope, Stability Chambers, Polarimeter, IR, DSC, TSC and GPC.
- Reaction calorimeter, Lasentec, Multimax (normal and high pressure), Easymax, autoclaves (SS & Hast-alloy up to 100 Kg/cm² pressure), Automatic Lab Reactor, Pressure Parallel Synthesizer, Rotavapour, Fluid Bed Drier, Spray Dryer, Lyophilizer etc.
- Process Intensification Lab has Micro reactors (Labflo and pilot) & Plug Flow Reactors
- All projects in R&D are properly coded and distributed to maintain strict confidentiality.
- All our Manufacturing and R&D Facilities are ISO-9001, EMS-14001 and OHSAS-18001 accredited. Further, our Nanjangud API facility is USFDA, MHRA and TGA approved.

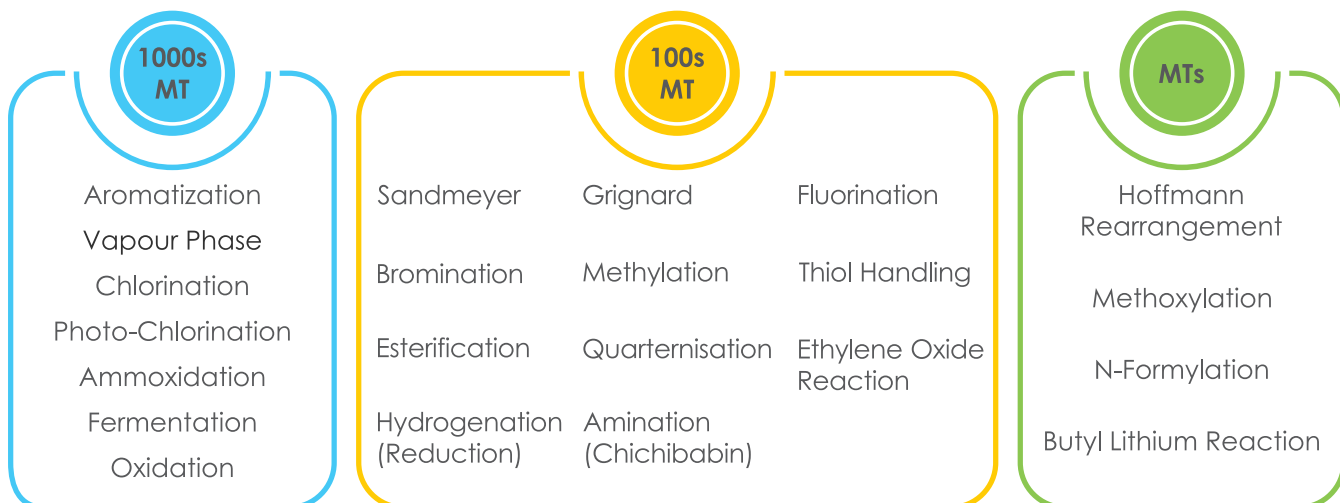


KEY TECHNOLOGIES

Key Chemistry and Technologies

- Specialized in handling Grignard reactions at 100's of MT/annum & Photochlorination at 1000's of MT/ annum, bulk chlorination facility at 1000's of MT/annum.
- Dedicated Fluorination facility with HF & KF.
- Hands on Experience of Chiral Synthesis, Cyanation & Oleum processes.
- Fixed bed and Fluidized Bed Catalytic reactors
- Distillation using highly efficient distillation Columns of 110-120 theoretical Stages.
- Handling Lachrymatics reactions at high volumes.
- High pressure reactors operating at 55 Bars.

Commercial Scale



Other Chemistries

- | | | |
|--|--|--|
| <ul style="list-style-type: none"> • Alkylation/Dealkylation • Beckmann Rearrangement • Manicch Reaction • PolyState studies • Cyclo Condensation • Claisen Condensation | <ul style="list-style-type: none"> • Phosphate Esters/POCl₃ Handling) • Nitration • Diazotisation • Dehydration • Alkali Metal Cyanide | <ul style="list-style-type: none"> • Transesterification • Hanzch Synthesis • Bio-transformations • Stereo Selective Hydrogenation • Balz-Schiemann |
|--|--|--|

Small Scale Specialty Chemistries



Small Peptides



Carbohydrates



Macromolecules



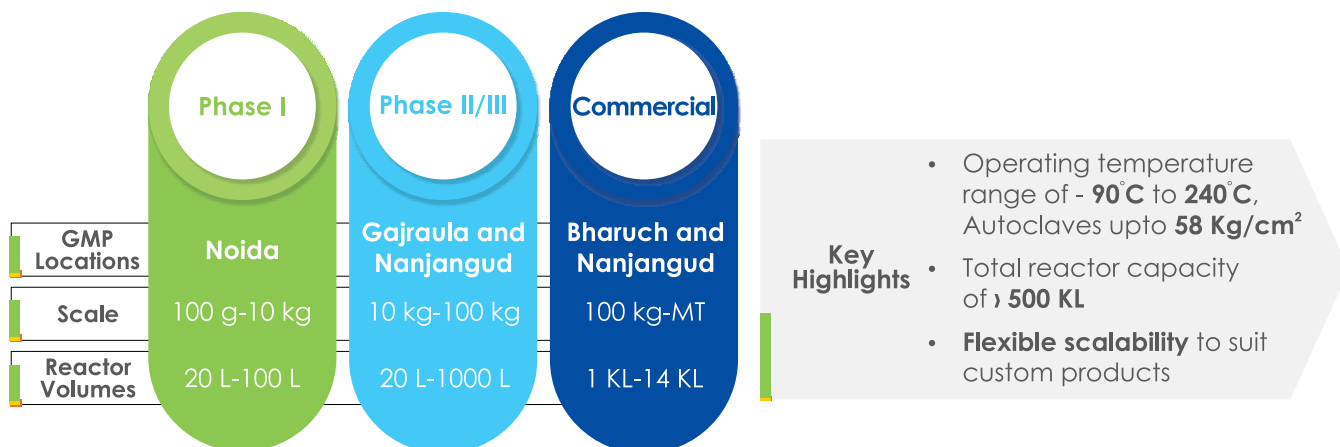
Nucleosides



Steroids

SCALE-UP & COMMERCIAL MANUFACTURING CAPABILITIES

In-phase to Commercial Manufacturing



Jubilant operates a well equipped Kilo-Lab and Pilot plant both at Noida and Gajraula (near Delhi) for Non-Regulatory steps synthesis and at Noida and Nanjangud (near Bengaluru) for Regulatory steps. The team has expertise to handle a wide range of operating conditions with flexible scales. Since inception, we have successfully supplied advanced intermediates/APIs and NCEs for molecules in early and late phase, and for commercial supplies. Jubilant's seasoned experts across process development, technology transfer and commercial execution teams collaborate to establish and deliver to your timelines.

Pilot plant

- Our cGMP Kilo-lab facility in Noida is designed with independent manufacturing suites having temperature, humidity and differential pressure controlled & ISO-8 (Class 100,000) clean rooms.
- Our GMP Compliant Pilot Plant facility in Gajraula operates with reactors ranging from 20 L to 630 L (Including glass, cryogenic reactors and autoclaves)
- Our cGMP Multipurpose Pilot Plant with PLC based Control System in Nanjangud has reactors ranging from 60-1000L, a Plug Flow reactor, a Lyophilizer and dedicated areas for drying and Powder Processing of APIs.

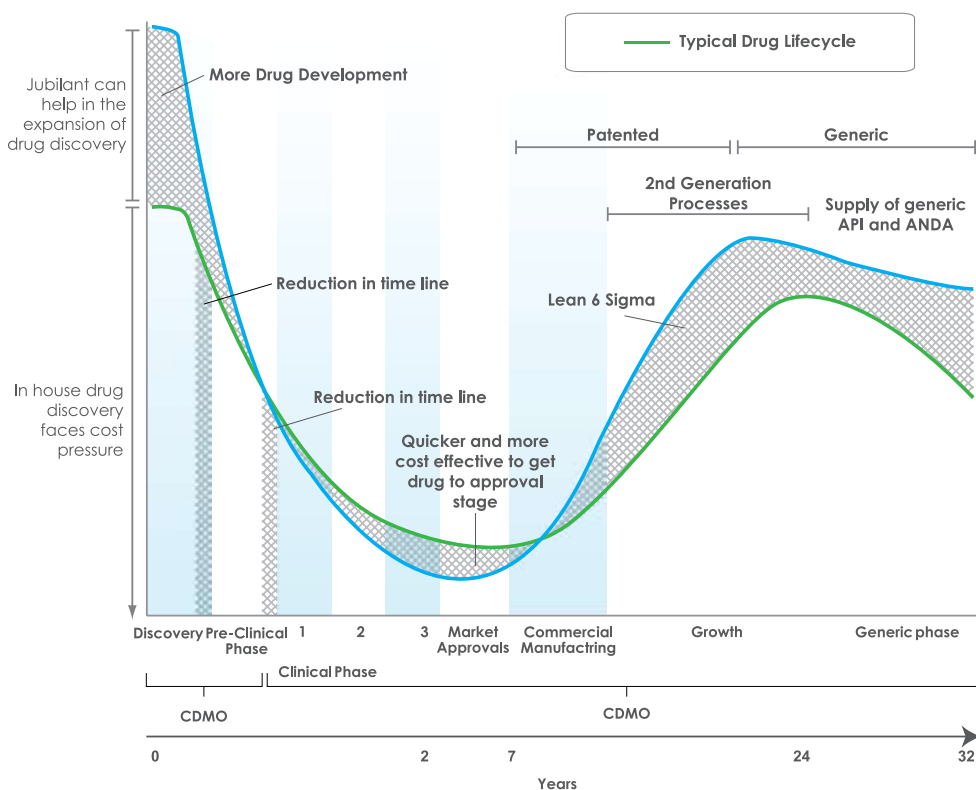
Commercial capabilities

- Commercial Plants have over 100 reactors (Mild Steel Glass Lined reactors (MSGL), Stainless Steel (SS) 304, 316, hast-alloy & Cryogenic)
- Wide range of process conditions (Temp. = -80C to 240C, absolute Vacuum) for multi-product manufacturing

GMP capabilities

- GMP Multipurpose RSM & Intermediate facility at our Bharuch location, for late phase and launch projects of customers and obtained a WHO GMP Certification.
- USFDA inspected API site at Nanjangud.
- Dryers - Vacuum dryers, FBD, Nauta drier, Lyophilizer
- 17 Clean Rooms (Class 100,000) for API powder processing.
- Temperature, humidity and differential pressure controlled (Building management system) areas & ISO-8 (Class 100,000) clean rooms with single -pass air control to avoid Cross contamination.
- Dedicated HVAC systems for each suite, powder processing area with quarantine, FG storage with pass box.
- SAP enabled and 21 CFR compliant computer systems

HOW JUBILANT CAN IMPACT THE LIFE CYCLE OF A DRUG?



JUBILANT'S CDMO ENABLERS



Environment Health and Safety

- Strong EHS initiatives and standards, focus on process and behaviour based safety
- Dedicated Occupational Health Centre; Zero discharge facility with proper handling of waste generation and effective treatment at ETPs. Valid hazardous waste authorization.



Business Excellence

- Implementation of Business Excellence (Lean 6 Sigma) initiatives across all functions for strong improvement of all processes.



Green Manufacturing Practices

- Use of **Green raw materials** (Corn/Cane Ethanol) for majority of products.
- Results in **lower carbon footprint** compared to petroleum based manufacturing.



Responsible Care 14001 Certification

- LSI business RC14001 certified under the American Chemistry Council's (ACC) Responsible Care® program for its Corporate Office in Noida and Gajraula Manufacturing Unit.



Sustainability

- Corporate Sustainability Reporting for over 10 years with Multiple GRI A+ ratings.

EcoVadis

EcoVadis

- Registered with EcoVadis for CSR evaluation with a gold rating. With this rating Jubilant's performance is among the Top 5% CSR companies globally.



Strict Quality and Regulatory Compliance

- Dedicated regulatory team ensures in-house technologies complies with global compliance and regulatory guidelines.

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You can also write to us for business specific inquiries at: CDMO@jubl.com

To know more log on to: www.jubl.com/lsi

