Contract Development and Manufacturing (CDMO)

ActiveSelection at Jubilant
Jubilant Life Sciences Ltd. with its strong Medicinal, Synthetic, Organic Chemistry and Manufacturing Capabilities has established itself as a single window resource for CDMO services. We strive to offer solutions across the entire Pharmaceutical Value Chain from Discovery to Market a few milligram to multimetric tons of specific products.

What is Jubilant ActiveSelection?
Jubilant Life Sciences’ CDMO Services acts as an outsourcing partner for many Life Science innovators and has adopted a new all-encompassing concept for its range of services.

The concept of Jubilant ‘Active Selection’ incorporates the unit’s own evolutionary history and sets milestones and objectives for the future.

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: End-To-End Service Provider

- R&D Centres: Noida and Bengaluru
- 500+ Scientists
- Pilot Plants: Noida and Gajraula
  - Reactors: 20+
  - Reactor Volumes: 20 L-1 KL
  - 50+ Scientists + Engineers
- 9 Multipurpose Plants for Non-GMP/GMP Intermediates and Actives
  - Reactors: 100+
  - Reactor Volumes: 1 KL to 14 KL
R&D Services
Jubilant provides Discovery, Medicinal Chemistry, Process R&D, Scale-Up and Manufacturing Services to Pharma and Life Sciences Innovators for Intermediates, both cGMP and non-GMP and APIs.

Discovery Services

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<th>Target Validation</th>
<th>Hit to Lead Generation</th>
<th>Lead Optimization and Preclinical Development</th>
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<td>TV: Bioinformatics, Target proposal (line-of-sight to IND), Target Validation (siRNA, tool cmpds, expression)</td>
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<td>Build: Target and pathway expression in human disease tissue, patient stratification</td>
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- **Hit to Lead:** HTS, Structural Biology (protein, X-Ray crystallography), Medicinal / Computational Chemistry, In-vitro / Cell biology
  - **Build:** Fragment and Lead Library synthesis, human cells (primary)

- **Lead Optimization & Preclinical Development:** Medicinal and Synthetic Chemistry, DMPK, In-vivo PD and disease models, scale-up preformulation, non-GLP Tox, D2M predictions
  - **Build:** Human pharmacodynamic / target engagement biomarkers

Developmental 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 IND filings.**
- **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) concepts to develop these processes.**

Facilities

- **Jubilant has R&D facilities at Noida, Bengaluru, Gajraula (near Delhi) with scale from mg to ton multi-scale.**
- **Fully equipped analytical laboratories with Advance equipment including 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, GPC.**
- **Reaction calorimeter, Lasentec, Multimax (normal and high pressure), Easymax, autoclaves (SS and hastelloy upto 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) and 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 Chemistry and Technologies

- Specialized in handling Grignard Reaction annually at 100s of MT annually and Photochlorination at 1000s of MT annually. Bulk chlorination facility at 1000s of MT annually.
- Dedicated Fluorination facility with HF and KF.
- Hands-on experience on Chiral Synthesis, Cyanation and Oleum processes.
- Fixed bed and Fluidized Bed Catalytic reactors
- Distillation using highly efficient distillation Columns of 110-120 theoretical stages.
- Handling Lachrymatory reactions at high volumes.

Commercial Scale

- Aromatization
- Vapour Phase Chlorination
- Photo-Chlorination
- Ammoxidation
- Fermentation
- Oxidation
- Sandmeyer
- Grignard
- Fluorination
- Bromination
- Methylation
- Esterification
- Quaternisation
- Hydrogenation (Reduction)
- Aminiation (Chichibabin)
- Ethylene Oxide Reaction
- Thiol Handling
- Hoffmann Rearrangement
- Methoxylation
- N-Formylation
- Butyl Lithium Reaction

Other Chemistries

- Alkylation/Dealkylation
- Beckmann Rearrangement
- Manicch Reaction
- PolyState studies
- Cyclo Condensation
- Claissen Condensation
- Phosphate Esters/POCl₃ Handling)
- Nitration
- Diazotisation
- Dehydration
- Alkali Metal Cyanide
- Transesterification
- Hanzch Synthesis
- Bio-transformations
- Stereo Selective Hydrogenation
- Balz-Schiemann

Small Scale Specialty Chemistries

- Small Peptides
- Carbohydrates
- Macromolecules
- Nucleosides
- Steroids
Seamless Developmental (Phase I, II & III) to Commercial Manufacturing

Jubilant has a state-of-art 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 upon the top-notch concept to commercialisation timelines.

Pilot plant

- Our cGMP facility in Noida is designed with independent manufacturing suites having temperature, humidity and differential pressure controlled and ISO-8 (Class 100,000) clean rooms for complete manufacturing operations.
- Our GMP Compliant Pilot Plant facility in Gajraula has reactors ranging from 20 L to 630 L (Including Glass assemblies and cryogenic reactors, autoclaves).
- Our cGMP Multipurpose Pilot Plant with PLC based Control System in Nanjangud has Plug Flow reactor, Lyophilizer & reactors ranging from 60 Ltr-1000 Ltr with 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, hastelloy and Cryogenic).
- Wide range of process conditions (temp-80°C to 240°C, absolute Vacuum) for multi-product manufacturing.

GMP capabilities

- GMP Multipurpose facility at our Bharuch location, for in-phase and launch projects of customers, will also be ready for WHO GMP Certification by early year 2018.
- USFDA Approved API site at Nanjangud to meet your regulated market requirements.
- 17 Clean Rooms (Class 100,000) for API stage powder processing.
- Temperature, humidity and differential pressure controlled (Building management system) areas.
- Dryers - Vacuum dryers, FBD, Nauta drier, Lyophilizer.
- Dedicated HVAC systems for each suite, Powder processing area with quarantine, FG reject material storage, FG storage with pass box.
- SAP enabled and 21 CFR compliant computer systems.
ActiveSelection for Success

The Life Cycle graph below gives a typical drug development life span and suggests schematically where Jubilant CDMO and Active Selection might be considered.

Jubilant is happy to share its skills and co-partner with other successful innovators.

How Jubilant Can Impact the Life Cycle of a Drug?

- **Typical Drug Lifecycle**
- **Jubilant Active Selection Drug Lifecycle**
- **Areas Jubilant Active Selection can improve in Lifecycle**
- **Active Selection Nodes**
Jubilant’s CDMO Enablers

Environment Health and Safety
- Strong EHS initiatives, focus on Process and Behaviour based safety
- Dedicated Occupational Health Center; Zero discharge facility with proper handling of waste generation and effective treatment at ETPs. Valid Hazardous waste authorization

Business Excellence
- Implementation of Business Excellence initiatives across all function for positive evolution of cost effective process for continual sustainability

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

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

EcoVadis
- Registered with EcoVadis for CSR evaluation with a gold rating. With this gold rating, Jubilant’s performance is rated as one of the Top 5% companies globally

Responsible Care 14001 Certification
- LSI business RC 14001 certified under the American Chemistry Council’s (ACC) Responsible Care® program for its Corporate Office in Noida and Gajraula Manufacturing Unit

Strict Quality and Regulatory Compliance
- Dedicated regulatory Team ensures In-house technologies to be non-infringing and Compliance to global regulatory norms