JUBILANT BIOSYS

Your CRDMO Partner in Science

CDMO Services

Our Vision

To be the leading Partner in Science globally, providing comprehensive drug discovery, development and manufacturing solutions to enhance patient well-being.

Our Promise

We will, with utmost care for the environment and society, continue to enhance value for our customers by providing innovative products and economically efficient solutions; and for our stakeholders through growth, cost-effectiveness and wise investment of resources.

Caring, Sharing, Growing

INSPIRE CONFIDENCE · ALWAYS STRETCH · NURTURE INNOVATION · EXCELLENT QUALITY

Scan to download the digital brochure

With a strong commitment to quality, supply chain and ESG considerations, Jubilant Biosys is emerging as a leading CDMO partner for pharma and biotech companies.

We help companies transition swiftly from preclinical drug development stage to clinical stages with flexible and strong scale-up capabilities.

- We can accelerate your drug candidate through end-to-end development and manufacturing, driving innovative partnerships across the value chain.
- We continue to invest in addition and upgrade of our technologies, processes, capabilities and expertise to offer reliable end-to-end integrated API development and manufacturing services.

Scientific Expertise — **Efficiency** — **Speed & Flexibility** — **Quality**

DEVELOPMENT SERVICES | **MANUFACTURING SERVICES**

IND Enabling Services / Custom Synthesis → Process & Analytical Development → Clinical Supply → Process Validation → Commercial Manufacture → Continuous Process Improvement

Comprehensive CDMO Services & Customised Solutions for your APIs

Development & Manufacturing Services for small molecule programs: from preclinical to phase III & commercial*

- Jubilant Biosys CDMO operates an FDA inspected facility that provides a full range of API development services for preclinical and clinical development, and supply cGMP API quantities from grams to multiple kilograms and metric tonnes.
- To support the development efforts, we provide API stability services, with chambers at room temperature, intermediate and accelerated conditions.

Early Development Solutions

- Custom synthesis
- Route scouting, development
- KSM & RM sourcing & development
- Polymorph screening & salt selection

Process Development, Validation, Scale-up & Tech Transfer

- Analytical method screening, development & validation
- cGMP starting material assessment
- Characterisation of impurities & crystal forms
- ICH compliant stability studies
- Process optimisation & development

Intermediate & API Manufacturing

- Pre-formulation & preclinical supply
- Clinical trial material
- Commercial manufacturing

Lifecycle Management

- Process improvement
- Cost improvement
- Yield improvement
- Regulatory filings & support

*All services are supported by dedicated Project Management Team.

Process R&D Capabilities

Jubilant Biosys offers comprehensive process research and development (PR&D) and manufacturing capabilities to support the early CMC campaigns of NCE programs. These combined capabilities ensure well-integrated execution of projects into the clinical phase.

- Route scouting, process design and optimisation
- Development and management of complex multi-step synthesis of APIs having many chiral centers
- DoE / QbD application
- Stereoselective synthesis
- Chiral separations
- Biotransformation
- Solid form development – salt and polymorph studies
- Salt screening and polymorph studies
- Low temperature reactions
- High Vacuum Distillation
- High pressure reactions (hydrogenations, reductive amination etc.)
- Process Intensification (continuous flow reactions) DoE application
- Data generation for process safety evaluation
- Kilo Lab (Capacity – 5,10 & 20L, heating range @ 200°C & cooling range @ -50°C)

Process R&D: Analytical Capabilities

- Method development
- Polymorph characterisation reaction monitoring support
- Generation of reference / working standards
- Stability studies as per ICH
- Nitrosamines method development and validation
- Forced degradation studies and development
- Impurity profiling and structural elucidation
- Documentation as per GLP/FDA requirements for technology transfer
- Center of excellence for Mass Spectrometry
- Genotox potential evaluation

Process R&D Instrumentation

- Reaction Calorimeter
- BRM Lasentec
- Autoclaves (SS & Hastalloy up to 100 kg/cm^2 pressure)
- Rotavapour

- Fluid Bed Drier
- Spray Dryer
- Lyophilizer etc.
- Micro Reactors (Labflo and pilot)
- Plug Flow Reactors

- LC HRMS
- NMR
- XRD
- LC-MS/MS
- Ion Chromatograph
- Particle size analyser
- Optical microscope
- Stability chambers

- Polarimeter
- FT-IR
- DSC
- GC-MS
- ICP-MS
- Prep-HPLC

In API R&D Center, our chemistry and analytical teams work together to manage projects at different stages of development.

R&D team provides wide range of CDMO services including custom synthesis, process route development and optimisation to enable scale-up of early stage compounds, up to commercial scale.

State-of-the-art R&D center in India at Nanjangud (Mysuru)

Experts in polymorphic characterisation and contamination, genotoxic and carry over studies, impurity profiling etc.

Team of dedicated and highly skilled scientists, including PhDs.

Equipped with latest equipment like LC HRMS, NMR, XRD, LCMS, GCMS, ICP-MS, etc.

Expertise in complex chemistries like Chiral separation, Low Temp reactions, Biotransformation, Stereo-selective synthesis, Process intensification (continuous flow reactions).

Seamless integration with multiple functions (Quality, Regulatory, Supply Chain & Project Management) to drive operational excellence.

Dedicated DoE/QbD Cell for bringing quality and process robustness during the product development.

GMP Kilo Lab at our API Manufacturing Facility

100g – 1 Kg Batch Size

- CDMO GMP manufacturing support
- Low volume clinical trial APIs
- GMP trials & validation

Advance Equipment Setup

- 10L, 30L Hastelloy reactors
- 10L All Glass Reactors
- Independent Temperature Control Unit
- 5L Nutsche Filter and 2 tray VTD

GMP Scale-up for scale up to 20 kg

Key Activities	Equipment
Different varieties of reaction vessels including a coil reactor for continuous reactions	Capacity: 4.3KL (~250 kg/month)
Distillation: Batch distillation, Atmospheric, Azeotropic high vacuum distillation	cGMP Plant 23 Reactor system
Filtration: Centrifuge/Nutsche Filter/Pressure Nutsche filter/ Agitated Nutsche filter & dryer	8 Glass line reactors 4 Hastelloy reactor 13 SS reactors
Drying: Vacuum Tray Dryer/ Agitated Nutsche filter & dryer/RCVD/FBD	2 Streams of clean rooms 250L SS Hydrogenator @ 10kg/cm^2
Milling & Size reduction: Air Jet Mill/Multi Mill/Sifter Absorption: Scrubber for hazardous fumes	20L Rotavapour 20L Lyophilizer
Hydrogenation: Separate area for hydrogenation Lyophilizer and Rotavaps for specific product requirements	200ml Coil reactor for continuous flow reaction 100L SS316L Reactor for cryo reaction (-150°C)

Seamless Scale-up & Technology Transfer

Jubilant Biosys offers reliable and efficient approach to transfer technology and our clients can leverage our proficiency, agility, and extensive capacities to seamlessly propel a product through all developmental and manufacturing phases.

Our dedicated tech transfer team with strong technical expertise helps facilitate speed to market as we collaborate with our partners to ensure successful process transfers, anticipating equipment capabilities and ensuring QbD principles.

Evaluation

- Review of technology for transfer
- Project scope defined
- Approval of scope of work

Technology Transfer Team

- Project kick off meeting
- Project plan/ schedule
- Communication structure
- Timeline for document review
- Change control
- Quality agreement

Knowledge/ Document Transfer

- Gap analysis
- Technical document review meeting
- Analytical method transfer
- Process demo batch
- Deviation analysis
- Quality agreement
- Stability studies

Technology Transfer Process

Process Transfer

- EHS assessment
- Logistics
- Operations
- Process hazard analysis
- Pre-startup safety review
- Training
- Process simulation batches
- Validation protocols
- Master batch records

Manufacturing Campaign

- Initial manufacturing campaign
- Process validation summary report
- Continuous improvement recommendations

Continuous Improvement

- Manufacturing data review
- Equipment / process optimisation
- Process monitoring
- Deviation-root cause analysis
- Corrective/ preventive actions

~2,70,000 sq. mts. site at Nanjangud, Mysuru, India with a wide range of facilities including cGMP kilo lab, cGMP pilot plant, stability and analytical labs, supporting QC / QA and EHS functions.

State-of-the-art API manufacturing facility fully compliant with cGMP, quality and safety requirements.

Multi-stream manufacturing blocks and a pilot plant having volumetric capacity of ~785 KL, 20+ clean rooms and 190 reactors ranging from 0.1 KL to 15 KL.

GMP Kilo Lab equipped with Hastelloy and glass reactors.

Experienced team of over 900 personnel.

One of the R&D centres is located within our API manufacturing site and facilitates seamless tech transfer and timely support to the operations team.

Manufacturing site at Nanjangud belongs to Jubilant Pharmova Ltd.

Equipment at Manufacturing Site

190 Reactors

54 Centrifuges

785 KL (Total)

10L-15KL (Reactor Capacity)

20 FBD

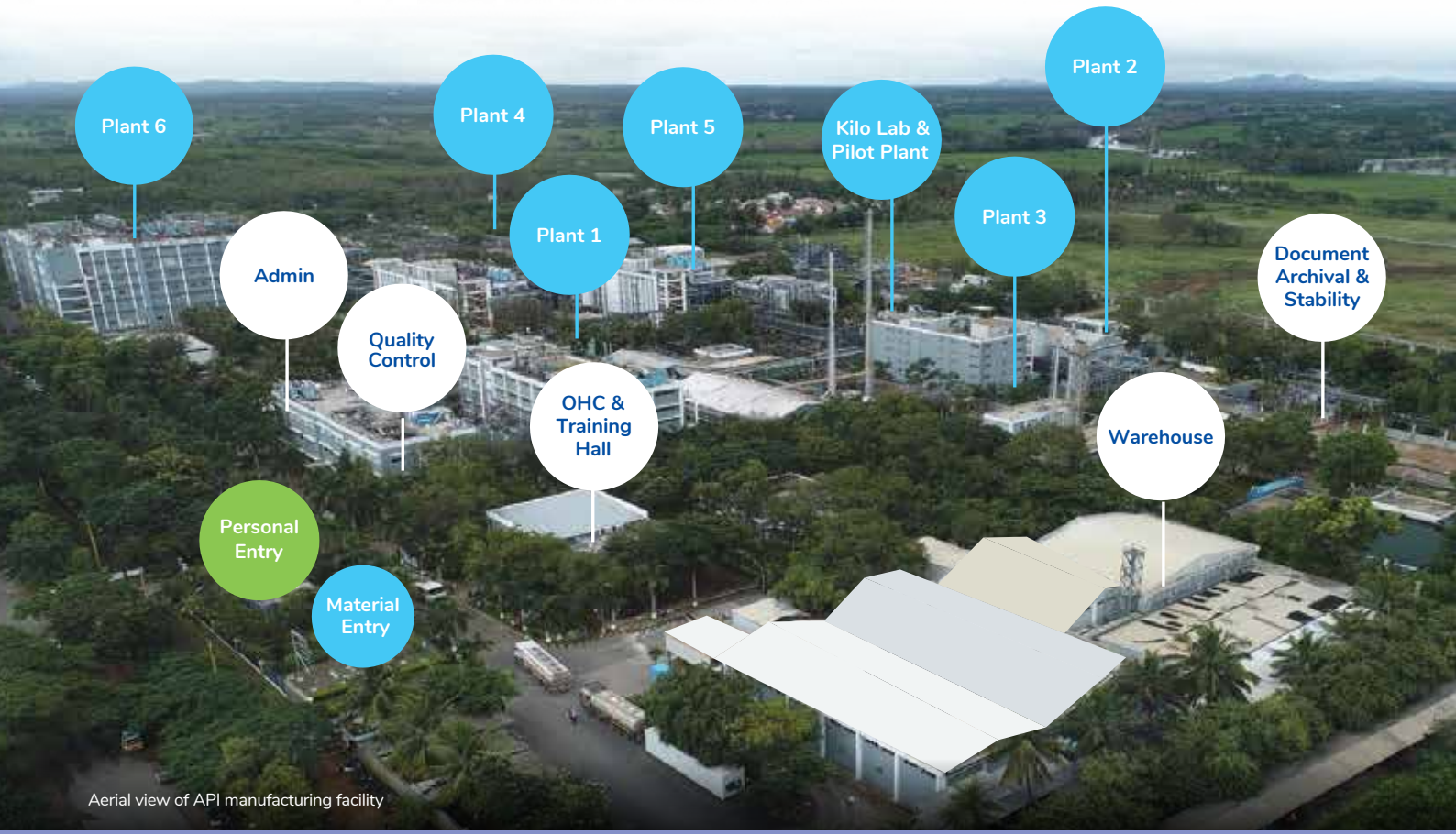
17 Air Jet Mills

API manufacturing facility successfully inspected by regulatory agencies across the globe.

U.S. FDA | EDQM | Health Canada | MFDS (Korea) | ANVISA (Brazil) | COFEPRIS (Mexico)

AFSSAPS | PMDA (Japan) | TGA (Australia)

Regulatory Affairs Cell at our manufacturing site possess in-depth knowledge of the regulatory processes across various geographies, including US, Europe, Japan, China, Brazil and Korea. With our in-house experience, we manage the entire regulatory process, including interactions with international regulatory authorities.

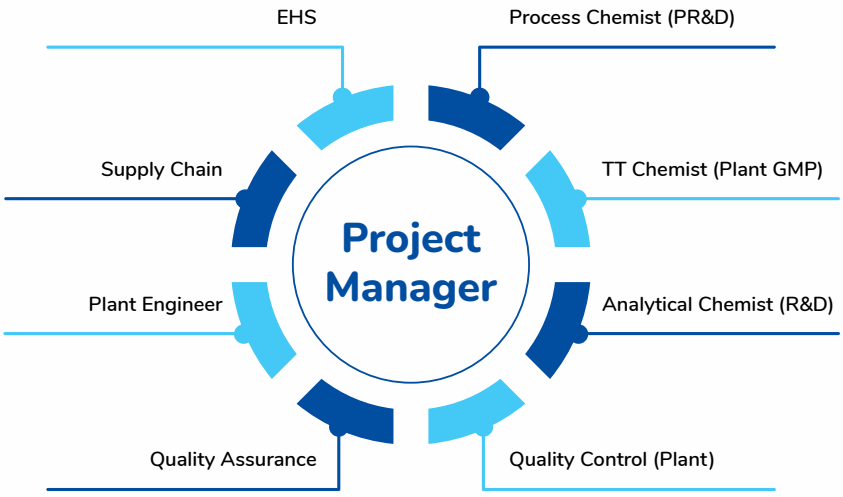


Aerial view of API manufacturing facility

"Currently belongs to said parent/associate company."

Our group of experienced and qualified project managers support and manage every contract manufacturing project from kick-off to closure.

- Experienced Project Manager as single point of contact for entire project life-cycle: team communication, schedule, scope, action, risk and issue escalation management.
- Process & Tech Transfer Chemists work on seamless hand-over from R&D familiarisationand process optimisation (what if studies) to plant scale-up.
- Dynochem simulation for plant equipment mapping and unit operation scalability.
- Analytical chemists for method development, validation and transfer to plant QC team.
- EHS for OEB and PDE classification and HAZOP evaluation.
- Plant engineer for equipment train set up and readiness.
- QA/QC to ensure GMP documentation, analysis and release.
- Supply Chain to ensure supply strategy and robustness.



Jubilant Biosys is pioneering sustainable CDMO solutions with a commitment to environmental stability.

Progressing towards exceptional ESG standards

55% Reduction
in specific greenhouse gas emissions

22% Reduction
in specific energy consumption

21% Decrease
in specific water consumption

Top 15% of World's best companies

SILVER 2022 ecovadis Sustainability Rating

Renewable Energy Target: 90%+ by FY27

Driving sustainable innovation for a brighter tomorrow.

Why choose Jubilant Biosys for CDMO projects?

- State-of-the-art production facility
- >20 years of manufacturing experience with proven expertise to operate large scale chemical operations
- 900+ MT reactor capacity
- 20+ clean rooms
- R&D centers with dedicated DoE/QbD cell for quality and process robustness
- Highly experienced team – PhDs with overseas exposure
- State-of-the-art analytical department, equipped with high-end equipment – XRD, LCMS, ICP-MS & LC HRMS etc.
- Diverse reactor capacity ranging from 10 L to 15,000 L
- Dedicated regulatory team to ensure process and technologies are compliant to global regulatory norms
- Focus on EHS: Zero discharge facility, valid hazardous waste authorisation and renewable energy
- Sustainable, cost optimal, and robust supply chain for competitive advantage and uninterrupted supplies
- Successful inspections by regulatory agencies across the globe including U.S.FDA, EMA, PMDA, and ANVISA

Our World-class Infrastructure

Integrated Drug Discovery Center (IDDC)

Bengaluru, India

Chemistry Innovation Research Center (CIRC)

GN, New Delhi India

Contract Development & Manufacturing Center (API CDMC)

GN & Noida, New Delhi India

Advanced Intermediate & API Site

NNJ*, Mysuru India

Why Choose Jubilant Biosys?

- Pharma-tailored Customer Approach
- Specialising in Small Molecules and Related New Modalities
- Science-driven Service Culture
- Innovation Supported by AI/ML
- 85+ Integrated Drug Discovery Programs Delivered
- Robust Supply-chain and Back-integration
- Highly Experienced Talent Pool
- World-class Infrastructure
- Global Presence
- Robust EHS & Quality System
- Advanced & Cost-competitive Operations Footprint

*Manufacturing site at Nanjangud (NNJ) belongs to Jubilant Pharmova Ltd.