

# CUSTOM DEVELOPMENT AND MANUFACTURING ORGANIZATION (CDMO)









## Jubilant Ingrevia's CDMO

Jubilant Ingrevia with its strong, Synthetic, Organic Chemistry and Manufacturing Capabilities has established itself as an important partner resource for Custom 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.

### Why Jubilant Ingrevia's CDMO?

Jubilant Ingrevia's CDMO aspires to be the partner of choice through reliable, sustainable & agile partnership by integrating itself into supply chains of innovator clients to support development, first scale up & commercialization of small molecule Intermediates & API's



#### **Our Value Proposition**



#### **Delivery concepts**

- Focus of project cross functional teams on Quality along with OTIF concepts.
- Design of projects towards reliable delivery timelines right from project conceptual stage (proposal submission).
- Key account management to address agile requirements from innovator clients towards technical, business & timeline aspects.
- Open client project reviews at agreed time intervals with stakeholders for curtailing anxieties build across stakeholder of project.

Dedicated & certified project Management team for seamless support.

### **RESEARCH DEVELOPMENT & TECHNOLOGY**

#### **Development Services**

- Route design, process development and process optimization for In-Phase clinical program & commercial small molecule compounds.
- Process improvement for commercial products.
- 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.

### **Research Facilities**

- Jubilant Ingrevia R&D facilities at Noida, Gajraula (near Delhi) & Bharuch facilities 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.
- Process Intensification Lab has Micro reactors (Labflo and pilot) & Plug Flow Reactors



#### **Key Technology**

- Specialized in handling Grignard reactions at 100's of MT/annum & Photo chlorination at 1000's of MT/ annum, bulk chlorination facility at 1000's of MT/annum.
- Dedicated Fluorination facility with HF & KF.
- Ketene & Diketene Derivatives production lines at 1000's MT/annum
- 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 Lachrymatic reactions at high volumes.
- High pressure reactors operating at 58 Bars.

### **Commercial Scale**



### **Other Chemistries**

- Alkylation/Dealkylation
- Beckmann Rearrangement
- Manicch Reaction
- PolyState studies
- Cyclo Condensation
- Claisen Condensation

- Phosphate Esters/POCl<sub>3</sub> Handling)
- Nitration
- Diazotisation
- Dehydration
- Alkali Metal Cyanide

- Transesterification
- Hanzch Synthesis
- Bio-transformations
- Stereo Selective Hydrogenation
- Balz-Schiemann

### SCALE-UP & COMMERCIAL MANUFACTURING CAPABILITIES

### In-phase to Commercial Manufacturing



Jubilant Ingrevia CDMO operates a well-equipped Pilot plant at Gajraula (near Delhi) for Non-Regulatory stages and Regulatory stages (cGMP) at Bharuch manufacturing facility. The team has expertise to handle a wide range of operating conditions with flexible scales.

We have successfully supplied RSM, Advanced intermediate 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 GMP Compliant Pilot Plant facility in Gajraula operates with reactors ranging from 20 L to 630 L (Including glass, cryogenic reactors and autoclaves)

#### **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 multiproduct manufacturing

### **GMP** capabilities

- GMP Multipurpose RSM, Intermediates & NCE facility at Bharuch location, for late phase and launch projects of customers & obtained WHO GMP certifications.
- Dryers Vacuum dryers, FBD, ANFD
- 3 Clean Rooms (Class 100,000) for Advance GMP Intermediates & 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.



### JUBILANT'S CDMO BUSINESS ENABLERS

#### **Corporate Office:**

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