

## Process Research & Development and Scale Up

**T**CG Lifesciences has aligned its chemistry service offerings to seamlessly support its clients in an integrated manner as their programs move across discovery and early development. Accordingly, we provide singletory/parallel medicinal chemistry synthesis during the SAR stage, rapid scale up for in vivo and early toxicology, route scouting, process optimization and kilo scale synthesis including cGMP supplies for regulatory toxicology and first-in-human studies.

We employ highly trained and dedicated scientists, engineers, and technicians, across process, all supported by an experienced QA team.

Our process research and kilo lab facility consists of a class 100,000 area with once through ventilation, integrated SCADA system, in process quality control, and optimal HAZOP with RC/DSC, process engineering allowing API production under cGMP guidelines. Working vessels include sizes up to 200L with operation temperature ranges of -80°C to +200° C. We have a GLP compliant analytical chemistry facility which provides full analytical support, impurity profiling, stability studies according to ICH guidelines, method development/validation, and process quality control. Our laboratories have ISO 9001:2008 certification and we are in the process of receiving an OECD certification. To support the activities above, we have an efficient and cost competitive purchase and logistics department with preferred vendor relationships, including a strategic alliance with a domestic contract manufacturing player.

We offer high quality and timely deliveries at attractive pricing to our global customers and partners. As a result, we have many repeat customers with multi-year collaborations. We were selected as one of the three top global CROs during an Innovation Challenge competition conducted by a global pharma major.

# Process Research & Development and Scale Up

## Operating space

- New route scouting
- Quick scale up of intermediates and products
- Process optimization
- Critical parameter determination
- Stretchability/PAR studies
- Holding studies

- Use of RC and DSC to study Heat accumulation, Adiabatic Temperature rise etc.
- "Stoessel Criticality" determination
- Stability studies



- cGMP material for "First in Human"
- Identification and qualification of vendors
- In process control
- Validated process and analytical methods
- Impurity profiling

- Scale up reactor design, vent size
- MOC, l/d ratio, stirrer type
- Guidance on tip speed, power requirement/unit vol etc.
- Phase separation, Filtration rate
- Drying pattern

- More than 50 PRD and scale up chemists.
- Multiple reactors from 20 to 200 L with different MOC.
- Operating temperature range  $-80^{\circ}\text{C}$  to  $+200^{\circ}\text{C}$ .
- Capabilities include use of lithium, aluminum, and other pyrophoric reagents.
- Various metal catalyzed reactions like Suzuki, Buchwald, Negishi, etc.
- Dedicated "GLP" certified analytical lab with 20 chemists.
- Dedicated QA team.



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