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500+ Clinical and Commercial Programs Delivered

At Aragen , we offer comprehensive chemical development solutions that ensure successful transition of your drug candidates from development to commercialization. Our dedicated team of experts and state-of-the-art facilities provide unparalleled support across every phase of chemical development, guaranteeing high-quality outcomes with efficiency and precision.

Our Chemical Development Capabilities

Process Development and Optimization

- Route scouting and selection
- Process optimization and scale-up
- PAT-enabled scientific and data driven crystallization studies (BlazeMetrics)
- Process engineering studies (scale up parameterization studies)
- Development of sustainable and cost-effective processes

Process Safety and Engineering Studies

- Hazard identification and risk assessment
- Process safety evaluation and optimization
- Development of safe operating procedures

Analytical Development and Stability Studies

- Method development and validation
- In-process control and monitoring
- Comprehensive impurity profiling

Manufacturing and IND/NDA Filing Support

- Clinical and commercial manufacturing
- 50 L to 12,500 L scale reactors
- Comprehensive documentation and filing support for IND/NDA and DMF submissions

Regulatory Approvals

Ministry of Food and Drug Safety

CDSCO

ISO

WHO

FDA U.S Food and Drug Administration

edqm

Pmda

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Integrated end-to-end DS/DP Solutions

- **Tox to Clinic (FIH):** Efficient transition from toxicology to First-in-Human trials
- **DS/DP Scale-Up:** Scalable DS/DP production from lab to commercial scale
- **Method Development:** Tailored methods for efficient manufacturing and quality control
- **Form Selection:** Optimized polymorph, salt, and solid-state form selection
- **Formulation Development:** Customized formulations for enhanced bioavailability and stability
- **Regulatory Solutions:** Regulatory-ready processes for seamless IND/NDA submissions

Chemistry and Technologies

Cross-Coupling Chemistry :

- Organometallic reactions like Heck, Suzuki, Negishi, Buchwald-Hartwig

Halogenation Chemistry:

- Fluorination/Bromination

Hazardous chemistry involving:

- Cyclopropanation
- Azides
- Cyanations
- Nitrations
- Lithium/Borane
- DIBAL/Sodium
- Borohydride
- Hydrogenations
- Exception - Use of $HF_{(g)}$ and $Phosgene_{(g)}$

Specialized areas:

- Amino acids, Peptides
- Carbohydrates, GalNAc
- Lipids, PEGylated lipids
- Amidites, Nucleosides and Nucleotides
- Pressure reductions/Reactions (up to 25 bar)
- Chemo/Biocatalysis
- Particle engineering studies
- Solid form screening and development
- Flow and Photo-Flow reactions
- ADCs linkers and toxins
- OLEDs

Operational Capabilities

Security of three sites at Hyderabad and Vizag to ensure timely delivery and business continuity

- 11 process blocks across three sites
- Total reactor capacity of 365 KL with the range of 20L to 12500L with the MoC range of SS, MS-GL and Hastelloy
- Hydrogenator (100L & 1kL- Hastelloy, 100L to 5kL- SS)
- Cryogenic reactors (100L to 10kL) operating up to -80°C
- Powder processing (jet mill, multimill, fleximill & pinmill/Hosokawa)
- cGMP and nGMP available HPAPI facilities handling up to $10ng/m^3$
- Operating pressure: full vac to 25 bar
- Operating temperature: -80°C to +200°C
- Comprehensive set of analytical capabilities performed 100% in-house (non-GMP & GMP)

Why Aragen?

- **4,300+** scientists incl. **450+** PhDs
- **400+** clients globally including late preclinical and commercial phases
- Partnering with **15** out of top **20** pharma companies
- **Active +100** early, late, and commercial projects (both non-GMP and GMP)
- Complete support for IND, NDA, DMF filing

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