

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





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 $\text{HF}_{(g)}$ 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 $10\text{ng}/\text{m}^3$
- Operating pressure: full vac to 25 bar
- Operating temperature: -80°C to $+200^{\circ}\text{C}$
- 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