

270+ Clinical and Commercial Chemical 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
- 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 Filing support

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

Regulatory Approvals





Integrated end-to-end API and Drug Product Solutions

- **Tox to Clinic (FIH):** Efficient transition from toxicology to First-in-Human trials
- **API Scale-Up:** Scalable API production from lab to commercial scale
- **Method Development:** Tailored methods for efficient production 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 submissions

Chemistry and Technologies

Cross-Coupling Chemistry :

- Heck, Suzuki, Negishi, Buchwald-Hartwig
- Fluorination/Bromination
- Hazardous Chemistry :
 - Azides
 - Cyanations
 - Nitrations
 - Lithium/Borane
 - DIBAL/Sodium
 - Borohydride

Specialised areas :

- Peptides, Amino acids
- Amidites, Nucleosides and Nucleotides
- Pressure reductions/Reactions (up to 25 bar)
- Chemo/Bio catalysis
- Flow and Photo-Flow reactions

Operational Capabilities

Cross-Coupling Chemistry :

- 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 60L to 12500L with the MoC range of SS, MS, GL and HA.
- Milling
- cGMP and nGMP available HPAPI facilities handling upto 0.1 mg/m³ (OEB 5)
- Operating pressure: full vac to 25 bar
- Operating temperature: -80° c to 170° c
- Comprehensive set of analytical capabilities performed 100% in-house (nGMP & GMP)

Why Aragen?

3,800+ scientists

400+ clients globally including late preclinical and commercial phases

Partnering with 16 out of top 20 pharma companies

74 NCE projects (both nGMP and GMP)

Complete support for IND, NDA, DMF filing

Let's begin the conversation

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