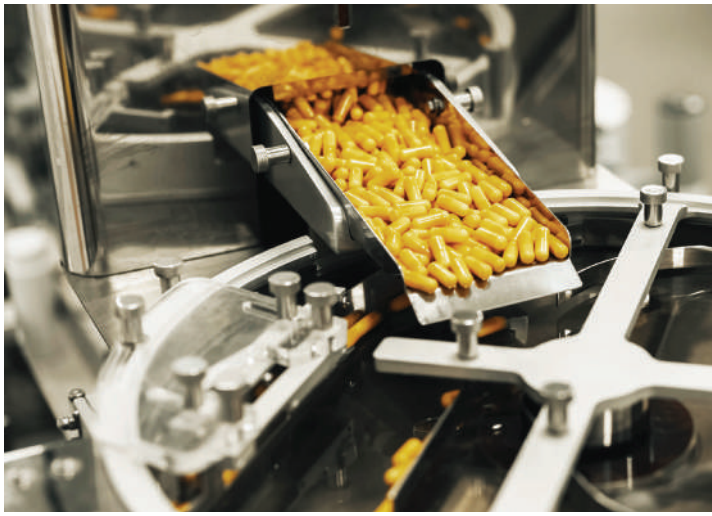
aragen.com

Formulation Solutions

Development & Clinical Manufacturing for Challenging NCEs



Accelerating your molecule from discovery to clinic, our integrated formulation services support everything from **preformulation to FIH (First-in-Human) and GMP clinical manufacturing**. With co-located teams and deep NCE expertise, we deliver clinic-ready drug products with speed, science, and scale.

Proof of Performance

200+ preclinical and clinical **formulations** delivered across oral, parenteral, inhalation, and semisolid dosage forms

250+ analytical methods developed and validated

50+ clinical products manufactured and supplied

Dedicated **pilot scale cGMP** suites specializing in **solid orals** dosage forms; routinely audited by global innovators

What We Do (End to End)

Preformulation & Developability (Preclinical)

- Physicochemical & solid-state profiling
- Salt/co-crystal screening, polymorph selection
- Scalable crystallization (PAT-enabled)
- Bio-relevant solubility mapping
- Risk-based developability assessments

Toxicology & PK Enabling Formulations (All Routes)

- Fit for purpose **suspensions, solutions, and powder**
- **Enabling technologies: spray dried dispersions, particle engineering** (micro and nano sizing), lipid-based and complexation-based systems to address poor solubility/bioavailability
- **Drug delivery systems:** micro /nano emulsions, **nanosuspensions**, liposomes, **in situ gels, microparticles/LAI, LNPs**, concepts where appropriate

Clinical Formulation Development (Phase Appropriate)

- **DS/DP integration:** from API to final dosage
- **Phase-appropriate specs, stress testing & bridging strategies**
- **CMC DP strategy:** DIC/DIB liquids, tablets, capsules (incl. neat, blend, pellets), select parenteral approaches
- **QbD-driven development & analytical validation**

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Clinical Manufacturing & Supply (GMP)

- **Solid orals (GMP):** immediate and modified release tablets (incl. mini tablets), DiC, DiB, film coated tablets, capsule filling (neat, blend, pellets)
- **Enabling oral formats: SDD powder** (as blend/capsule/tablet), micronized API fills, Nano-sizing technologies
- **Select parenteral/ophthalmic** formats at R&D scale; tech transfer options as needed
- **Integrated services:** labelling/packaging, IMP/clinical supply, and stability per ICH where applicable

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Challenges We Solve	Solutions We Deploy	Solutions We Deploy
Low solubility / poor PK	SDD, nanosuspensions, lipidic systems	Higher bioavailability and predictable PK
Polymorph/form instability	Solid form screening, PAT crystallization, controls	Stable DP and smoother scale up
Dose uniformity at low load	Precision dosing, mini tablets, optimized blends	Content uniformity and flexible titration
Bridging from tox to FIH	Developability assessment, stress stability, excipient/closure compatibility, risk based specs	Right first time FIH
Tight timelines	Integrated DS/DP workflows, parallel analytics, co located facilities	Faster time to clinic

Quality, Compliance & Documentation

- Phase appropriate **GMP** and **QA** oversight
- Global audit readiness
- **Method validation** aligned to development phase
- **ICH stability** and clinical supply packages
- Robust **CMC documentation** to support IND/IMPD filings

Flexible Engagement Models

- Standalone or integrated **DS/DP programs**
- **FFS** or **FTE**, scaled to your needs
- Flexible **tech transfer** and scale-up options; transparent governance and PMO

Why Aragen

- **20+ years of NCE expertise:** Preformulation and clinical development
- **Co-located functions:** Chemistry, biology, DMPK, materials science, formulation, analytics, and GMP clinical manufacturing
- **Speed + Science + Scale:** Rigorous science, accelerated timelines, and scalable solutions

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