

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)

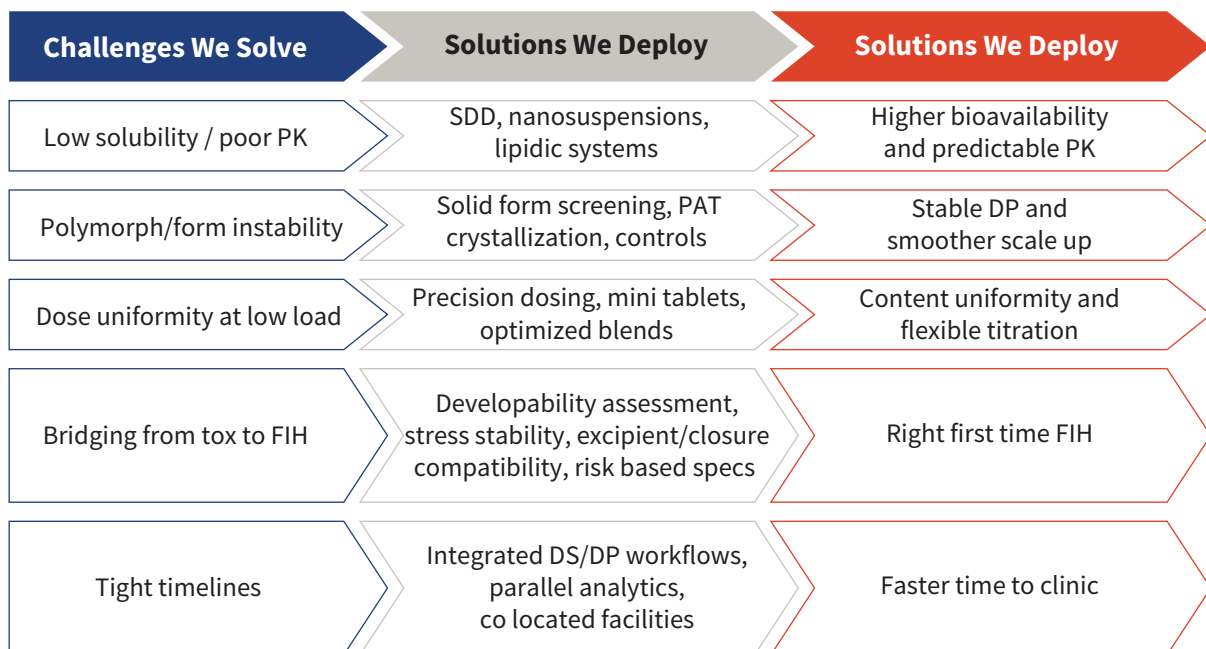
- **DS/DP integration:** from API to final dosage
- **Phase-appropriate specs, stress testing & bridging strategies**
- **CMC DP strategy:** DIC/DIB liquids, tablets, capsules (incl. neat, blend, pellets), select parenteral approaches
- **QbD-driven development & analytical validation**

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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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/IMP/DP 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