

# Driving your lead candidate to clinic

Early phase clinical supply solutions are core to Ardena. Our expertise includes phase appropriate development and manufacturing under cGMP conditions of both drug substance (DS) and drug products (DP).

We support customers with short lead times by centralizing and developing processes, analytical methods and formulations in-house. Recognized for our regulatory track record and with a multidisciplinary team of DS, DP and RA CMC experts, we expedite your project collaboratively to meet your first-patient-in targets.

Navigating you through drug development



ARDENA

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## Drug substance

### Services

- Route scouting
- Process development and scale-up
- Analytical method development & validation
- ICH stability studies
- GMP-manufacturing

### Technology highlights

- Chromatographic purification
- Ion exchange chromatography
- Ultra- and nanofiltration
- Short-path distillation
- Peptide development and manufacturing

## Drug substance / Drug product interface

### Services

- Solid form screening & selection
- Crystallisation process optimization
- Powder flow & compaction analysis
- Preformulation

### Technology highlights

- Single-crystal structure determination
- High-throughput & high-resolution X-ray diffraction (XRPD)
- Focused beam reflectance measurement (FBRM)
- Real-time dissolution profiling

## Drug product

### Services

- Formulation development
- Process development & scale-up
- Analytical method development & validation
- ASAP and ICH stability studies
- GMP-manufacturing
- Packaging & labelling
- Clinical logistics

### Technology highlights

- Oral solid dosage forms like capsules and tablets
- Spray drying
- Lipid-based formulations
- Liquid-based formulations such as nanosuspensions, emulsions and nasal sprays
- Liquid-filled capsules
- Coating technologies
- Fluid bed granulation
- Overencapsulation