

Phase appropriate drug substance manufacturing

Ardena navigates your small molecule API project through route scouting, development and manufacturing under accelerated timelines. From small scale to technology transfer for commercial scale production (up to approx. some metric tons/year), we produce your drug substance with commitment to cGMP conditions. Ardena provides leading chemical synthesis experience and manufacturing infrastructure including advanced purification technologies. Your Ardena contact will engage with you to ensure your development and manufacturing timelines are met.

Navigating you through
drug development



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
Customized novel excipients such as lipids, surfactants and polymeric linkers

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