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.
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