Facilitating clinical trial success for drug products

Ardena has extensive experience formulating drug products for early development. The breadth of our technologies enables us to provide a drug product that can be consistently prepared and accurately dosed, and that allows for mastering of potential solubility and bioavailability challenges.

A highly skilled team, actively supported by CMC experts, approaches formulation options in function of risk assessment frameworks. By navigating through a complex regulatory environment, a complete IMPD dossier is delivered on time.
**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
- High potency capabilities
- Lipid-based formulations
- Liquid-based formulations such as nanosuspensions, emulsions and nasal sprays
- Liquid-filled capsules
- Coating technologies
- Fluid bed granulation
- Overencapsulation

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