

# Precision in Commercial Manufacturing



## Scale-up and supply for oral solid dosage forms

Advancing from development to commercial supply requires more than scale. It demands a robust, compliant, and predictable manufacturing environment supported by experienced teams and proven processes.

Ardena delivers oral solid drug products at commercial scale through a structured, science-led approach. With integrated development, tech transfer, and manufacturing capabilities, we ensure continuity from early stages to market supply, reducing risk and accelerating timelines.

Our commercial manufacturing services combine strong regulatory expertise and advanced technologies to enable secure, scalable supply for global programs.

### Key highlights:

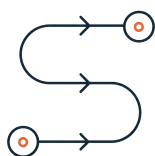
- GMP manufacturing approved by FDA, EMA, MHRA, PMDA, ANVISA and other agencies
- DEA controlled substance capabilities
- Proven delivery from development through commercial manufacturing
- Multi-site manufacturing footprint ensuring supply continuity
- US Foreign Trade Zone (FTZ) advantages



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## Reliable Supply at Commercial Scale



### End-to-end delivery

- Structured tech transfer and scale-up from clinical to commercial
- Process validation and regulatory readiness built in
- Lifecycle management and continuous improvement
- Dedicated project teams ensuring predictable execution



### Scale and technology

- Commercial batch sizes up to 500 kg with lifecycle scalability beyond
- QbD-driven processes ensuring robustness and reproducibility
- Advanced platforms including hot melt extrusion and modified release
- Broad oral dosage form expertise



### Quality and compliance

- Strong global inspection record across major regulatory agencies
- Integrated QA/QC systems with full digital traceability
- Commercial-ready analytical and release testing
- Regulatory support aligned with global submissions



### Supply resilience

- US-based FTZ enabling duty deferral and cost optimization
- Simplified API importation and reduced cross-border complexity
- Regional manufacturing footprint supporting continuity of supply
- Reduced exposure to global supply disruptions and trade uncertainties

**Partner with Ardena for reliable commercial manufacturing and supply**

Contact us to discuss your program



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