

# Scalable drug product manufacturing



## Supporting your drug product scale-up, optimization & commercial manufacturing

Quotient Sciences specialize in guiding drug products through the critical transition from late-stage optimization and registration batch manufacturing through to full commercial readiness. Our approach is built on rigorous science, regulatory alignment, risk-based focus, and operational flexibility.

Our highly skilled technical staff and successful quality audits from multiple global inspection agencies, ensure your drug product manufacturing is fully compliant and ready for an accelerated commercial launch.

With a proven track record working in niche market areas including oncology, orphan/rare diseases, and pediatric indications, we ensure your product reaches patients faster, without compromise to quality or speed.

### What can Quotient Sciences' commercial manufacturing do for me?

- ✓ Structured Technical Transfer Methodology
- ✓ Risk Based CMC Strategy Planning
- ✓ SME Module 3 Review & PAI Readiness
- ✓ Registration and Validation Batch Manufacturing
- ✓ Analytical Method Lifecycle Management
- ✓ ICH Stability Programs
- ✓ Continuous Process Verification & Improvement

## Agility built into every batch size

Niche programs, such as for orphan drugs and pediatrics, require flexibility to establish a successful, resilient commercial product supply chain. We offer commercial manufacturing solutions customized to meet the needs of your program. Rather than dictating minimum batch sizes, we partner with our clients to offer flexible, versatile, service options to accommodate the needs of your program.

### With batch sizes ranging from less than 1kg to over 400kg, we can accommodate a variety of solid oral dosage form designs including:

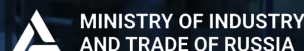
- ✓ Immediate Release Tablets
- ✓ HPMC and Gelatin Capsules
- ✓ Mini-tablets/Granules
- ✓ Amorphous Solid Dispersions
- ✓ Powders for Oral Suspension
- ✓ Matrix Modified Release Tablets
- ✓ Protective & Modified Release Coatings

Whether seeking US in-shoring, evaluating dedicated supply chains for specialized markets, ensuring business continuity, or simply managing the product life cycle, Quotient Sciences is prepared to support. Our facilities also support secondary commercial site selection.



## Global quality, local confidence

Our global commercial manufacturing facilities deliver quality pharmaceutical products, supported by robust quality systems and inspection success. Commercial markets currently being served include the US (FDA), Europe (EMA), Japan (PMDA), Brazil (ANVISA), Russia (EUEA), and China (NMPA).



### Scaling science into solutions

Our subject matter experts have the both the scientific knowledge and industry experience to optimize your manufacturing process and create a late stage and commercial control strategy to meet regulatory expectations. Every program is assigned to dedicated technical personnel who provide risk-based feedback throughout the product life cycle.

### Our experience across a range of OSD manufacturing technologies includes:

- ✓ Bin and V-Shell Powder Blending:
- ✓ Roller Compaction Dry Granulation
- ✓ High Shear Wet Granulation
- ✓ Fluid Bed Drying
- ✓ Powder Tamping Encapsulation
- ✓ Tablet Compression
- ✓ Aqueous Pan Coating
- ✓ Hot Melt Extrusion
- ✓ Powder Auger Bottle Filling
- ✓ High Potency API Handling

### Milestones are our mission

With over 30 years of experience guiding late-stage and commercial drug programs, our project management team delivers more than oversight—we deliver confidence. Whether transferring between our sites or interacting with other service providers, we ensure your program remains streamlined, compliant, and on schedule.

Every commercial program regardless of scale, benefits from a customized dashboard that tracks key performance indicators (KPIs) in real time for adaptive planning and cross-functional communication. These dashboards are paired with quality score cards to demonstrate continuous improvement throughout the product lifecycle.

Through proactive communication, risk-based decision-making, and a unwavering focus on what truly matters, our commercial project management keeps your priorities front and center.

### High potency handling

With dedicated high-potency handling suites and a robust contamination control strategy, we offer state-of-the-art containment manufacturing designed for even the most demanding compounds. Our facilities feature flexible and hard containment technology options with additional engineered controls that meet our Level 5 Performance Based Level of Exposure Control (PBLEC) standards—capable of handling exposure levels down to 0.1 µg/m<sup>3</sup>.