



Information sheet

Drug product scale up and commercial manufacturing

A Trusted Commercial Manufacturing Partner

Quotient Sciences manufactures a range of dosage forms - from the simple to the complex – with a track-record of working with higher-value products that may require lower batch sizes in the market; such as those for oncology therapies, orphan/rare diseases, and pediatric indications.

As a trusted development and manufacturing partner, Quotient Sciences recognizes that speed, flexibility & agility are essential for establishing a successful commercial product supply chain. We offer commercial manufacturing solutions tailored to the specific product and market needs. Rather than dictating minimum batch sizes to our customers, we partner with our customers to offer flexible, versatile manufacturing space, resource and scheduling to accommodate the needs of your individual project.

Our highly skilled staff and experience from multiple successful launches, ensures your drug product gets the focus it needs to accelerate through registration batches, process validation and onwards to a successful commercial launch.

Dosage forms

Quotient has vast experience across an array of dosage forms. Manufacturing for registration batches and commercial supply, includes:

- > Solid oral dosage forms
- > Oral solutions and suspensions

Our commercial batch sizes include:

- > From less than 1kg to over 500kg for solid oral dosage forms
- > Up to 350L for liquid formats using an automated filling line
- > In addition to manufacturing products for NDA, ANDA, MAA and JNDA registration, the Quotient team can also support 505(b)(2), CBE-30 and other filings.

Process scale-up

We have the knowledge and experience to efficiently scale your process to meet the requirements of your later stage clinical and commercial drug product needs. Quotient has a team of dedicated process experts who support the identification of critical process parameters to allow a robust scale-up to meet the required scale.

Registration batch manufacturing and process validation

Whether you are preparing for ANDA, NDA, MAA or Japanese NDA, Quotient has the expertise and regulatory approval to manufacture your registration and validation batches for the U.S., U.K., Europe, Brazil and Japan.



What can Quotient's commercial manufacturing do for me?

- > Manufacturing solutions tailored to the product and market needs.
- > Cost-effectively and rapidly produce high quality drug products
- > Scale up seamlessly with advanced technology and expertise in a wide variety of drug products
- > Leverage expertise with high potency molecules

Project management

Quotient Project Management has over 30 years of experience in supporting drug programs that are in late stage development and commercial. Our project managers will ensure your commercial readiness by providing end-to-end support from concept and project scoping, to project delivery. And where projects transition across our sites, or intersect with other service providers, we'll make the process seamless for you.

High-potency handling

Take advantage of our state-of-the-art containment manufacturing for handling high-potency products as well as controlled substances. Quotient's handling area for high-potency compounds features isolator technology and state-of-the-art engineered controls. Our containment classification is based on the Performance-Based Level of Exposure Classification (PBLEC). We can handle a PBLEC level 5 (or down to 0.1 ug/cubic meter) dependent upon the type of compound, dosage form and batch size.

Whether you need to manufacture a new commercial product or extend your commercial supply chain for existing product, Quotient has the capabilities, quality and experience to help you achieve your goals.

Getting you to commercial launch, fast.

Who is Quotient Sciences?

Quotient Sciences is a drug development and manufacturing accelerator providing integrated programs and tailored services across the entire development pathway. Cutting through silos across a range of drug development capabilities, we save precious time and money in getting drugs to patients. Everything we do for our customers is driven by an unswerving belief that ideas need to become solutions, molecules need to become cures, fast. Because humanity needs solutions, fast.

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