How do I scale up my product for commercial launch?

Commercial Manufacturing at Quotient Is Your Answer

Quotient Sciences is a global player in commercial manufacturing of small molecule products including niche therapies like oncology, orphan and pediatric indications. Our commercial manufacturing facility, located in Philadelphia, is designed to handle your high-potency compounds.

The facility consists of over 43,000 square feet of analytical laboratories and drug product manufacturing space, including cGMP suites and non-GMP development laboratories. We offer 14 manufacturing suites including four high-potency containment suites each with dedicated air and separate HVAC systems. We handle batch sizes ranging from less than 1 kg to over 500 kg.

Our commercial batch size capabilities include:

- Up to 500 kg for solid oral dosage forms
- Up to 350 L for liquid formats using an automated filling line

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 and Japan.

Quotient has vast experience across an array of dosage forms that we manufacture for registration and commercial supply, including:

- Oral solutions and suspensions
- Solid oral dosage forms

In addition to manufacturing products for NDA, ANDA, MAA and JNDA registration, the Quotient team can support 505(b)(2) and CBE-30 filings.

What can Quotient's commercial manufacturing do for me?

- 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 in high-potency manufacturing, niche therapies and orphan drugs

Quotient Sciences
Assess. Adapt. Accelerate.

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Phase III clinical and commercial drug product supply

Quotient can support all aspects of your drug product supply for Phase III clinical studies and commercial supply for all major dosage forms including:

- Solutions and suspensions
- Drug in bottle, drug in capsule
- Formulated drug in bottle or capsule
- Immediate, sustained and modified release tablets

High-potency GMP manufacturing

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.

When you need late stage or commercial manufacturing for a simple or complex drug product, **Quotient is your answer**.

Who is Quotient Sciences?

At Quotient, we work to accelerate the development of new drugs for patients around the world by providing formulation development, clinical pharmacology, and clinical and commercial manufacturing to the pharmaceutical and biotech industry. We have innovated a new approach to drug development called Translational Pharmaceutics® that reduces costs and shortens timelines by integrating formulation development, real-time adaptive GMP manufacturing and clinical research for the continuous improvement of development programs. We answer the industry's tough questions through our individual services and integrated solutions.

Learn how Quotient is your answer.

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