

How do I ensure flexibility in my manufacturing process and batch sizes to meet my clinical trial design?

Quotient is your answer.

Clinical Trial Manufacturing at Quotient Is Your Answer

Understanding that early phase clinical testing is a pivotal milestone in the development of your drug product, Quotient Sciences offers clinical trial manufacturing, testing and certification services designed to meet your individual requirements. Our innovative history of building integrated GMP and GCP programs enables us to provide you with a streamlined, flexible approach to drug product supply that reflects your clinical study design and timeline. We understand the time and cost pressures you face during early phase evaluation and work with you to ensure a rapid, seamless path from development to clinical trial supply.

Recognizing your need to move rapidly through clinical development, we have the capability to efficiently scale up drug product manufacturing processes to meet the demands of your later clinical trial requirements and ensure seamless transition to larger scale manufacturing and drug product commercialization.

Dosage forms

We offer you manufacturing and testing services for all major dosage forms including:

- Solutions and suspensions
- Drug in bottle, drug in capsule
- Immediate, sustained and modified release tablets
- Solubilized formulations including amorphous (spray-dried and HME) dispersions, micronized and lipidic formulations

Routes of delivery

We have extensive experience developing and manufacturing drug products intended for all major routes of delivery:

- Oral (solid and liquid forms)
- Topical
- Inhaled (pulmonary, nasal)
- Rectal

High-potency API handling

Take advantage of our state-of-the-art containment manufacturing for handling high-potency product, featuring isolator technology and engineered controls. Our containment classification is based on the Performance-Based Level of Exposure Classification (PBLEC), allowing us to handle levels 1 through 5 (or down to 0.1 ug/cubic meter) dependent upon the type of compound, dosage form and batch size.



What can Quotient's clinical trial manufacturing do for me?

- Improve cost efficiency and reduce loss with real-time adaptive GMP manufacturing for niche, orphan and pediatric studies
- Deliver efficient manufacturing, packaging and release of your clinical trial products to reflect your clinical trial design
- Leverage our expertise in high-potency manufacturing



Quotient Sciences

Assess. Adapt. Accelerate.

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Phase I, Phase II and Phase III clinical trial manufacturing

We support all aspects of drug product supply for your Phase I, II and Phase III clinical studies:

- Manufacture of all major drug product dosage forms in our FDA- and MHRA-approved facilities
- Multilanguage label design (including translation)
- Packaging including bottles, blisters, tubs and tubes
- Post-study drug return and reconciliation
- Randomization and blinding
- Schedule I - IV controlled substance handling
- Shipment logistics and supply tracking
- Storage and distribution capabilities (ambient, refrigerated and frozen)
- Supply chain management to your clinical site

Real-time adaptive manufacturing

Quotient's history and expertise in integrating manufacturing with clinical dosing enable us to manufacture, package and **release products in a matter of days or weeks rather than months**. Our approach maximizes flexibility around batch size and timing supply to your selected site in response to emerging clinical data or patient recruitment — all without affecting the availability of your drug product. Our approach can be used across all drug product types.

Global supply management

We deliver clinical supplies to support your Phase I and II clinical studies, managing the packaging, multi-language labeling and door-to-door logistics in accordance with your clinical design. Our clinical trial supply team works with you to design the most efficient process for drug product supply to your central hub or clinical sites including the provision of bulk drug product or individual patient kits.

When you need maximum flexibility in your clinical trial drug supply, **Quotient is your answer.**

Quotient has reached a clinical trial supply milestone, providing over 2,000 drug products to 60 unique clinical sites in hospitals and contract research organizations worldwide.

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.



Translational
Pharmaceutics®



Formulation
Development



Clinical Trial
Manufacturing



Clinical
Pharmacology



Commercial
Manufacturing



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