

Information sheet

Flexible product manufacturing and clinical supply for all phases of development

Clinical Trial Manufacturing

Tailored to meet the needs of the clinical trial design

Quotient Sciences manufactures a range of dosage forms – from the simple to the complex – and we partner with our customers to provide a streamlined, flexible approach to drug product manufacturing and supply that reflects your clinical study design and timeline.

We offer a variety of manufacturing and clinical supply approaches from real-time adaptive manufacturing, bright stock and just-in-time (JIT) approaches to traditional large batch production. We'll help you move rapidly through clinical development with the capability to efficiently scale up 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?

- > Use a variety of manufacturing approaches to make only the product you need, flexible on-demand
- > Tailored manufacturing, packaging and clinical trial supplies to reflect your clinical trial design
- > Improve cost efficiency by reducing drug substance and drug product waste
- > Leverage our expertise in high-potency manufacturing

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**. Combined with bright-stock and JIT approaches, we maximize 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.

Global clinical supplies

We understand the challenges of managing clinical trials at numerous sites, in multiple countries. Quotient can ease the headache of global product supply logistics and accelerate your proof-of-concept timeline. We'll develop and manufacture your drug product, and then seamlessly integrate into a flexible packaging, labelling & distribution strategy, tailored to your clinical trial.

Managing the packaging, multi-language labeling and door-to-door logistics, 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.

Getting drug product to patients, 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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