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Quotient Sciences

Molecule to cure. Fast.™

Information sheet

Integrating compounding and GMP manufacturing for seamless product supply

Start FIH with Fit-for-Purpose and Continue to POC with a Patient-Ready Drug Product

Quotient provides integrated solutions to help clients achieve their proof-of-concept milestone quickly, saving them precious development time and money. Begin your First-in-Human (FIH) Phase I testing with a fit-for-purpose, simple pharmacy preparation, and then seamlessly transition to a Phase II ready formulation for proof-of-concept (POC) all within one organization. As demonstrated in a recent Tufts CSDD publication[1], our integrated approach has been proven to accelerate development times by more than 12 months.

Integrating Compounding & GMP Manufacturing for Seamless Product Supply

Get into the Clinic Quickly

Formulation Development

- Biopharmaceutics Led
- API Characterization
- In-Silico Modeling
- Formulation Screening
- Preclinical Prototypes

Start with Fit-for-Purpose Phase I Dosage Form

Bridge Formulations in the FIH Protocol

First-in-Human Trials

- Pharmacy Compounding
- GMP Product Manufacturing
- Simple to Complex Products
- Solution to Solid Oral Dosage
- Immediate to Modified Release

Continue with Patient-Ready Phase II Dosage Form

Supply Product Seamlessly to Patients

Proof-of-Concept and Beyond

- Formulation Finalization
- QbD Process Development
- Clinical Manufacturing
- Packaging & Distribution
- Scale Up to Commercial

The only partner with pharmacy compounding and GMP manufacturing options in-house

1. Tufts Center for the Study of Drug Development, Tufts University School of Medicine. (2019) Assessing the Financial Impact of Translational Pharmaceutics®: A Platform for Accelerating Product Development. Boston, MA.

Quotient's Three Step Approach

1. Quickly start your FIH trial with a fit-for-purpose pharmacy preparation

- Use a cost-effective dosage form for the FIH trial which provides maximum dose flexibility to achieve Phase I objectives

2. Bridge formulations within the same FIH protocol

- Evaluate formulation technologies and dosage forms in order to select a patient-ready formulation to move forward with

3. Seamlessly supply product to start POC patient trials

- Have immediate clinical trial material supply ready for packaging and shipment

Pharmacy compounding offers customers a quick and simple way to start FIH clinical testing, without the need for extensive CMC investment or API consumption at this early stage of development. Dose preparations can be made in "real-time" giving our clients the flexibility to make quick and informed changes to the dose or formulation based on human data in order to respond to changes in the FIH protocol design.

The longer-term goal however is to advance the molecule into Phase II patient trials. At Quotient, our compounding pharmacy, GMP manufacturing and clinical pharmacology services are fully integrated and led by industry leading project managers, helping clients to successfully bridge to a patient-friendly GMP drug product for their POC trials. All of this can be achieved in a compressed timeline and without the need for multiple vendors.

For those with challenging molecules, clients can leverage Quotient's biopharmaceutics and formulation development expertise. Quotient's manufacturing capabilities include immediate and modified release capsules and tablets, and a full range of solubility enhancement technologies including lipidic systems, micronization, spray drying and hot melt extrusion, to produce solubilized intermediates and final dosage forms.

Quotient's Compounding Pharmacy Facility

Quotient's state-of-the-art, 2,500ft^2 compounding pharmacy is located within our 144 bed clinical pharmacology facility in Miami, FL. The pharmacy contains high-potency handling capabilities and can support a full range of dosage forms including solutions, suspensions, drug in capsules, and sterile preparations. Our pharmacy is fully integrated with Quotient's global pharmaceutical development and GMP manufacturing facilities in the US and UK.

Technical & Quality Parameters Comparing Quotient's Compounding Capabilities with Traditional Pharmacy Compounding

Operation	Pharmacy compounding	"Quotient" pharmacy compounding
Standards	UPS 795 and 797	UPS 795, 797 and 800
Hazardous drugs	x	✓
Stability / shelf life	Short-term	Short-term or long-term
Quality oversight	Pharmacist	GCP quality system / pharmacist
Facility (room)	ISO 5 & 7 (Aseptic)	ISO 5 & 7 (Aseptic) ISO 7 & 8 (non-Aseptic)
ID testing	x	✓
Environmental monitoring	✓ (Aseptic only)	✓✓ (Aseptic and non-aseptic)
Cross contamination control	✓	✓

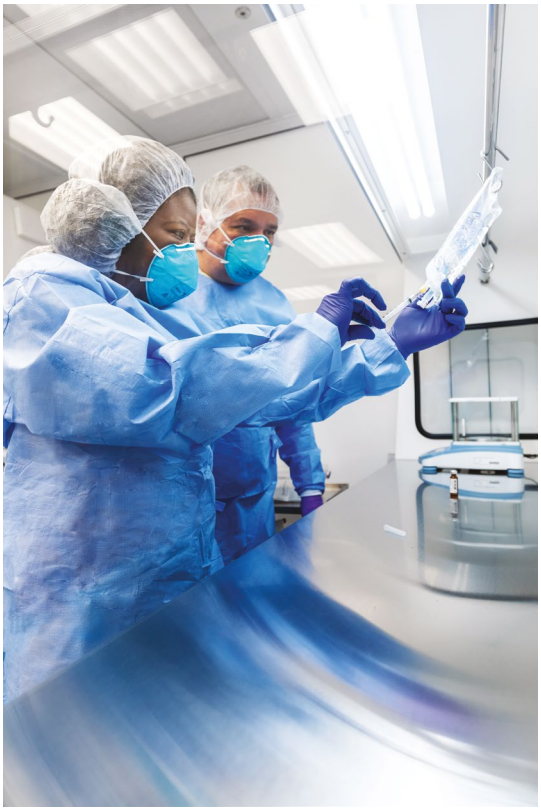
Dosage Forms Supported - Comparing Quotient's Compounding Capabilities with Traditional Pharmacy Compounding

Operation	Pharmacy compounding	"Quotient" pharmacy compounding
Dispensing / blinding	✓	✓
API in capsule / bottle	✓	✓
Powder in capsule / bottle	x	✓*
Liquid in capsule	x	✓*
Solution / suspension	✓	✓
Aseptic preparation ID testing	✓ (low volume)	✓ (low volume)
Over encapsulation	✓	✓
Solubilised forms	x	✓*

* Supplied by Quotient's in-house GMP manufacturing capabilities

Benefits of Using an Integrated Pharmacy-Manufacturing Approach

- Quickly & cost-effectively start clinical testing with a fit-for-phase pharmacy preparation
- Manage CMC investment in dosage form development appropriately as a molecule progresses and key elements are de-risked
- Select an appropriate dosage form for the FIH trial which provides maximum dose flexibility to achieve Phase I objectives
- Evaluate different formulation options and select a lead system to move forward
- Develop and bridge to a solid oral drug product for patient trials within the same program of work
- Seamlessly start Phase II trials on-time with immediate supply of clinical trial material
- Minimize the number of vendors and simplify the supply chain
- Manage quantities of API and drug product costs



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