Quotient Sciences

TRANSLATIONAL PHARMACEUTICS®

First-in-Human to Proof-of-Concept

Translational Pharmaceutics® Approach

Quotient Sciences' Translational Pharmaceutics® approach enables First-in-Human studies by re-engineering the transition of your drug molecule into clinical development and shortening the timeline to Proof-of-Concept.

How?

Quotient's Translational Pharmaceutics® platform integrates formulation development, real-time adaptive GMP manufacturing and clinical testing so that drug product manufacture occurs immediately prior to dosing. Each manufacture of drug product is therefore conducted in response to emerging clinical data. This approach delivers significant benefits to the development team.

Re-engineering the pathway into clinical development

Conventionally, to achieve the shortest timeline to first-subject-first-dose (FSFD), formulation development and clinical drug product manufacture are conducted prior to completion of pivotal toxicology studies.

With Translational Pharmaceutics®, key pharmaceutical development activities and costs can be deferred until after completion of toxicology studies, with no negative impact on FSFD date. Our team of experts will:

- Review your biopharmaceutics data package
- Develop formulations suitable for FIH and beyond
- Use in-silico modeling and simulation to predict human dose and pharmacokinetics (PK)
- Generate and compile the regulatory data package

Benefits of FIH studies enabled by Translational Pharmaceutics®

	Conventional	TP Enabled
Pharmaceutical development	~6 months	1–3 months
Stability program	>3 month	<7 days
Dose strengths	Multiple, pre-detemined	Determined in real-time
Dose units	>5000	<500
API consumed	>500g	<100g
Number of drug products	Single	Multiple
Vendor management	Multiple	Single

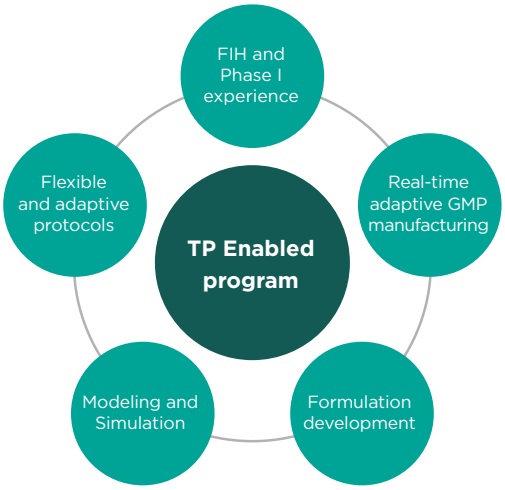
First-in-Human to Proof-of-Concept

Clinical conduct

Real-time adaptive GMP manufacturing offers maximum flexibility, within the single and multiple ascending dose phases without detracting from the key objectives of safety, tolerability and PK assessments.

- All dose and formulation decisions are based on emerging clinical data
- Typical cycle times are 10 – 14 days between each dose escalation
- Exact dosage strengths are manufactured, enhancing the precision of the study
- Multiple formulation technologies can be easily investigated and compared within a single, adaptive clinical protocol
- The risk of early termination of the program due to sub-optimal exposure is reduced

Accelerated pathway to POC



Shortening the timeline to POC

The ability to screen alternative formulations within the FIH study allows the selection of an appropriate drug product for immediate manufacture and seamless supply into the multiple dose and POC studies.

Whether the POC study is performed at Quotient or specialist sites internationally, Quotient will supply product directly to the patients, removing the need to transfer the manufacturing process to a 3rd party contract manufacturer.

Timelines can be further compressed by incorporating the healthy volunteers and POC phases into a single multi-part protocol, which can be approved following a single regulatory submission within typical Phase 1 timelines. We have delivered POC data in less than 12 months for multiple clients and therapeutic areas.

How do I benefit from this approach?

Our Translational pharmaceutics® approach is applicable to all drug molecules, all routes of delivery and all types of formulation – whether “fit for purpose” or requiring sophisticated technologies.

Formulation development can be performed by your organization, by a third party vendor, or by us.

The first step is to meet with you to understand your development plan and design a program of work to achieve your objectives.

Edinburgh | Miami | Nottingham | Philadelphia | Reading

Call UK: +44 (0)115 974 9000 | Call USA: +1-800-769-3518
info@quotientsciences.com | www.quotientsciences.com

Quotient Sciences