

Information sheet

# **Translational Pharmaceutics®**

# Our flagship platform for accelerating drug development

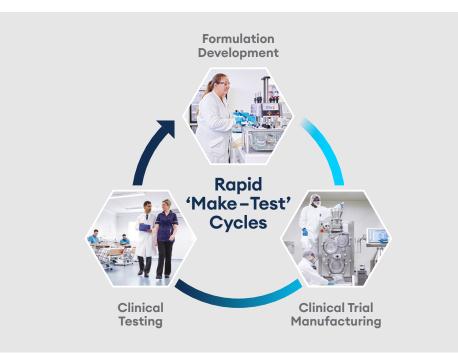
Translational Pharmaceutics® is our unique platform which accelerates drug development by integrating drug substance, formulation development, realtime manufacturing and clinical testing. Global pharmaceutical and biotech companies have used Translational Pharmaceutics since 2008 on over 500 drug programs.

#### What is the major benefit?

Speed – saving you money and getting your product to patients faster. On average our platform saves 12+ months of time and at least \$100 million in R&D costs over traditional drug development, according to a recent Tufts CSDD white paper.\*\*

#### Why is Translational Pharmaceutics different?

Led by a single project manager, our approach integrates many activities at one service provider so that you streamline outsourcing and management. With rapid "make-test" cycles, drug products are manufactured, released and dosed in days or weeks rather than months, shortening the time to clinical data.





### What can Translational Pharmaceutics® do for me?

- Shorten your timelines by > 12 months
- > Reduce your R&D costs by > \$100 million
- Achieve total financial gains of > \$200 million (per approved drug)
- Conserve up to 85% of your drug substance
- Facilitate real-time decision making based on emerging clinical data
- Deliver flexibility to adjust formulation compositions within your study
- Simplifies the supply chain and reduces R&D costs and risk

# Where is Translational Pharmaceutics used in drug development?

Translational Pharmaceutics advances molecules across the full development cycle from first-in-human (FIH) to commercial product. Key applications include:

- 1. Shortening of the timeline from candidate selection to clinical development
- 2. Fast-tracking molecules from FIH to Proof of Concept (POC)
- 3. Development and optimization of clinical formulations, including:
  - a. Enhanced solubility
  - b. Modified release
- 4. Life cycle management of late-stage and marketed products
- 5. Evaluation of novel drug delivery technologies for all routes of administration

## Translational Pharmaceutics will help you to:

- Bridge from FIH preparations to GMP drug products for POC trials
- Switch from simple solutions and suspensions to solid oral dosage forms
- > Evaluate and select solubilization technologies
- > Optimize modified release systems
- > Improve taste, palatability, and acceptability
- > Develop pediatric dosage forms
- > Change routes of delivery
- > Develop combination products
- > Understand quality by design (QbD) of variables
- > Develop in-vitro in-vivo correlations (IVIVC)

### How can I perform a Translational Pharmaceutics program?

Our team will design a customized program to deliver your objectives in the most timely and cost-efficient way. Contact us today to find out more: info@quotientsciences.com

### **Related Articles or References**

\*\*Tufts Center for the Study of Drug Development. Accessing the Financial Impact of Translational Pharmaceutics. Available at: https://www.quotientsciences.com/solutions/translational-pharmaceutics/tufts-report/

Cheeti, S, Hou, HH, Nelson, E, et al. Application of a novel 'make and test in parallel' strategy to investigate the effect of formulation on the pharmacokinetics of GDC-0810 in healthy subjects. Pharm Res 2018;35:233. https://doi.org/10.1007/s11095-018-2516-0.

Moreno O, Butler T, Zann V, Wilson A, Leung P, Connor A. Safety, pharmacokinetics, and pharmacodynamics of ME-401, an oral, potent, and selective inhibitor of phosphatidylinositol 3-kinase P110∂, following single ascending dose administration to healthy volunteers. Clin Ther 2018 Nov;40(11): 1855-1867. https://www.ncbi.nlm.nih.gov/pubmed/30458930.

Angi R, Solymosi T, Erdősi N, Jordan T, Kárpáti B, Basa-Dénes O, Ujhelyi A, McDermott J, Roe C, Mair S, Ötvös Z, Molnár L, Glavinas H. Preparation, pre-clinical and clinical evaluation of a novel rapidly absorbed celecoxib formulation. AAPS PharmSciTech 2019 Jan 25;20(2):90. https://www.ncbi.nlm.nih.gov/pubmed/30684094

### 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.

Alnwick > Edinburgh > Miami > Nottingham > Philadelphia > Reading

