

How do I save >12 months of development time?

Translational Pharmaceuticals[®] is your answer.

Translational Pharmaceuticals[®] Accelerates Product Development

Quotient Sciences helps you achieve your goals by enabling precise formulation development, streamlined manufacturing, quick pivot to clinical data and a significantly faster transition through drug development.

What is Translational Pharmaceuticals?

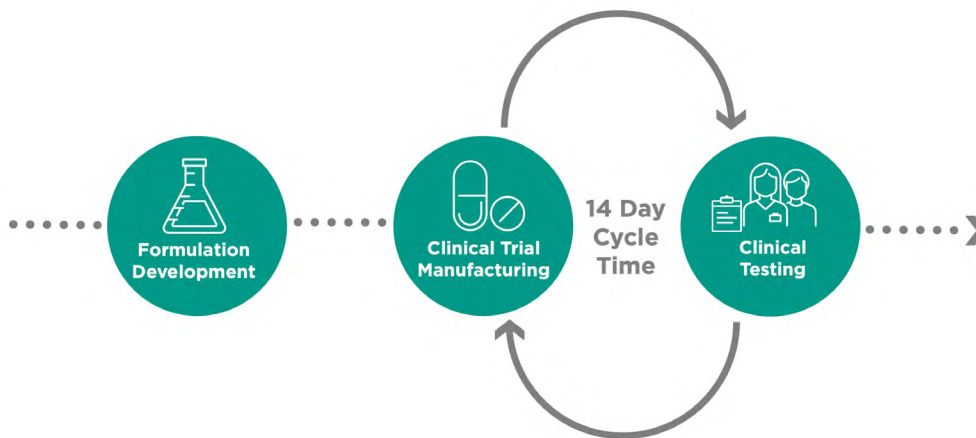
Quotient's unique platform accelerates drug development by integrating formulation development, real-time manufacturing and clinical testing. Global pharmaceutical and biotech companies have been using Translational Pharmaceuticals for 10 years across over 400 drug programs.

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 Pharmaceuticals different?

Led by a single project manager, our approach integrates many activities at one service provider so that you streamline outsourcing and management. Drug product is manufactured and released in days rather than months, minimizing stability data needed to get clinical data. Emerging data can then inform formulation changes, which then launches our 14-day 'make and test' cycle. Science-rich decision making, driven by clinical data, not only optimizes the formulation but also multiplies the likelihood for success.



What can Translational Pharmaceuticals 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
- Streamline vendor management and simplify your development plan

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

Translational Pharmaceutics will help you to:

- Bridge from FIH pharmacy 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@quotientosciences.com.

Related Articles or References

**Tufts Center for the Study of Drug Development. Accessing the Financial Impact of Translational Pharmaceutics. Available at: <https://www.quotientosciences.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 α , 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>.

