Quotient Sciences

Molecule to cure. Fast.™

Information sheet

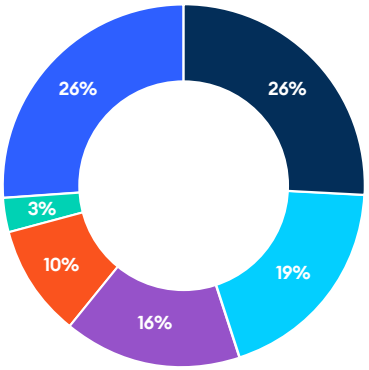
# PBPK Modelling & Simulation

Quotient is a leading expert in the application of physiologically based pharmacokinetic (PBPK) modelling and simulation (M&S) science to drug development. Using GastroPlus™ we advise our clients on the potential *in vivo* performance of drugs and formulations to inform product and clinical development strategies. Whether working in a consultancy relationship or as part of an integrated program of work, our PBPK expertise is underpinned by our unique and extensive experience in pharmaceutics, biopharmaceutics, DMPK and clinical research.

## What are the benefits of PBPK M&S?

- Development of mechanistic models to predict and model drug and formulation performance *in vivo*.
- Identification and management of developability risks for molecules with suboptimal physicochemical and biopharmaceutics properties.
- Determination of critical-to-performance attributes of the drug product for rational product design.
- Define informative experiments and avoid unnecessary ones.
- Applications throughout the development life cycle.
- Systematic product design, lowering development costs and reducing time to market.
- Widely accepted by regulators and has already featured in many EMA and FDA regulatory submissions.

## PBPK Project Experience




- **FIH Predictions** – 26%
- **IVIVCs** – 19%
- **QbD Modelling** – 16%
- **MR Formulation Design** – 10%
- **Pediatrics** – 3%
- **Others** – 26%

"Others" include risk assessing formulation changes, changing route of administration, assessing effect of transporters.

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## Why Quotient's M&S Consultancy?

- **Development Experience:** M&S activities conducted at Quotient span early clinical development through to product life cycle management.
- **Comprehensive Portfolio:** Project portfolio includes first in human, modified release, IVIVCs, QbD, pediatrics plus more.
- **Performance Excellence:** In 5 years, we have completed >30 M&S projects for >20 pharma and biotech clients, providing unique insights into critical product development challenges.
- **Technological Know-how:** Our experts have extensive experience across the scientific disciplines that underpin PBPK, gained from working with a diverse range of compounds and formulations.
- **Flexibility:** We work in either a standalone consultancy capacity, or integrated with a formulation or clinical program conducted at Quotient. As development progresses we can support downstream model refinement and validation.
- **Regulatory Experience:** Models built by Quotient's scientists have been used in regulatory submissions.
- **Customer Focused Support:** We understand and support changing customer needs at each stage of development, as models evolve and new data emerge.

## Development Lifecycle

| Candidate Selection to First-in-Human | First-in-Human to Proof-of-Concept | Proof-of-Concept to Commercialization |
|---|---|---|
| Physchem parameter predictions for discovery lead compounds | Model directed rational formulation development | Biowaiver submissions |
| Interpreting drug transporter and enzyme Assays | Predicting regional drug absorption | Generating or Developing an IVIVC |
| Preclinical PK modelling | Simulating food and PPI effects | Clinically relevant dissolution specification setting |
| Early stage identification of rate limiting factors | Optimizing CR/MR formulations | Virtual bioequivalence predictions |
| Predicting first pass effects | Simulating effect of API particle size | Justifying late stage formulation changes |
| Interpreting Non-linear PK | Safe Space Design | Supporting process related changes (SUPAC) |
| Amorphous vs. Crystalline API predictions | Pediatric PK Modelling | Regulatory queries assistance |

**Quotient's M&S services – integrated programs or consultancy**

Alnwick › Edinburgh › Miami › Nottingham › Philadelphia › Reading

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