Quotient Sciences

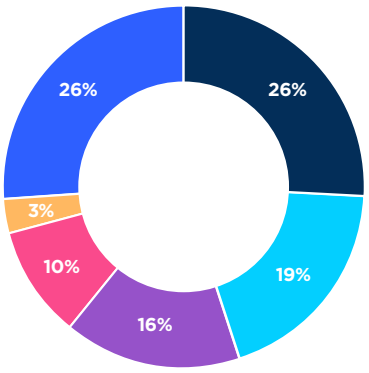
PBPK Modelling & Simulation

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

Edinburgh | Miami | Nottingham | Philadelphia | Reading

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