

How do I select
the right formulation
for my molecule?

Quotient is your answer.

Formulation Development at Quotient Is Your Answer

Quotient Sciences has almost 30 years of experience developing a breadth of formulations across a range of indications. Our innovative approach to formulation development integrates drug product development with clinical evaluation and combines this with our experience with over 1,000 molecules at all stages of drug development.

From preclinical and first-in-human (FIH) dosage forms to optimization of your drug products for late stage development and market following clinical evaluation, we work with you to develop the most appropriate formulation based on the physicochemical and biopharmaceutics properties of your drug molecule, the intended route of administration and the phase of development.

With our state-of-the-art facilities in the U.S. and U.K., we offer you a formulation development service that draws on the extensive experience of our formulation and biopharmaceutics scientists to identify the phase-appropriate, optimal formulation of your molecule.

Whether you need rapid formulation development services or a customized program, **Quotient is your answer.**

Formulation design

Quotient Sciences' formulation teams have vast experience across an array of drug product formats for administration via oral, inhaled, topical, rectal and parenteral routes.

Solid oral dosage forms

- API or formulated API in a bottle or capsule
- Immediate, modified and sustained release tablets
- Orally disintegrating tablets (ODT)

Orally inhaled and nasal dosage forms

- Dry powders
- Solutions
- Suspensions

Parenterals

- Intravenous (IV)
- Intramuscular (IM)
- Subcutaneous (SC)

Gels, ointments and creams

- Rectal
- Topical

Solubility-enhanced dosage forms

- Complexes in a bottle, capsule or tablet format
- Lipidic vehicles
 - Self-emulsifying drug delivery systems (SEDDS) in a capsule format
 - Self-microemulsifying drug delivery systems (SMEDDS) in a capsule format
- Micronized API in a bottle, capsule or tablet format
- Spray-dried dispersion in a bottle, capsule or tablet format



What can Quotient's formulation development do for me?

- Identify and address critical formulation issues quickly
- Optimize the performance of your formulation
- Support your formulation development from preclinical to clinical evaluation



Quotient Sciences

Assess. Adapt. Accelerate.

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Preformulation screening

Quotient Sciences' experienced material scientists can support your preformulation screening to allow selection of your drug candidate for preclinical evaluation.

Our rapid screening approach uses techniques such as particle size analysis, solubility screening, amorphous content and candidate stability to identify your lead candidates, which can then be developed into formulations for preclinical evaluation as either simple solutions/suspensions or more complex formulations.

By rapidly screening excipients and selecting appropriate formulations, you can begin preclinical studies in a matter of weeks rather than months.

First-in-human formulation development

Quotient Sciences' focus is on delivering the most appropriate formulations to expedite your clinical program, through dosing within our Phase I clinical facilities or at an external site. We support rapid progression to your first-in-human evaluation ensuring that your lead drug product can be seamlessly transitioned through development and scale-up following confirmation of molecule safety and tolerability. Our formulators' experience is built on years of work integrating formulation development and clinical evaluation. As a result, our development is based on an understanding of the intended indication including drug products designed for chronic dosing or for pediatric populations.

Poorly soluble drug formulation development

Poor solubility is increasingly prevalent in drug pipelines across the industry — about 70 percent of drugs that enter development possess insufficient aqueous solubility for adequate and consistent gastrointestinal absorption.

With nearly 30 years of experience, Quotient has established a broad suite of technologies and formulation approaches including amorphous dispersions and lipidic formulation development. Our approach allows us to dramatically speed up the product optimization to improve oral bioavailability and deliver the solubilized drug molecule in your required drug product format.

Modified release formulation development

The demand for modified release formulations is driven by many factors related to both patient and therapeutic need. For most conditions, patients generally demand either once or twice daily treatments, requiring sustained drug concentrations throughout the treatment period. Modified release formulations are designed to deliver your drug over a defined period of time and/or to a particular region of the body. By doing this, drug delivery can be optimized to balance therapeutic need, manage AE profiles and reduce dosing frequency, which contribute to improved patient compliance.

Quotient Sciences has extensive experience in designing modified release formulations, from gastro-retention to sustained and pulsatile release formats.

Analytical services

Access to experienced analytical scientists and state-of-the-art equipment is critical to the success of your drug development program. At Quotient Sciences, we pride ourselves on providing the best analytical support, delivering candidate screening, drug product analysis and phase-appropriate method development and validation.

We have extensive experience in the testing of drug products from preclinical development through to commercial drug products including:

- Preclinical prototype evaluation including biorelevant characterization of your solid oral dosage forms
- Excipient compatibility to support your prototype selection
- Finished product testing including purity, dissolution and physical characterization
- ICH stability testing of your early and late stage drug products

We understand your analytical objectives throughout the drug development process and work with you to ensure that appropriate methodologies are available at all stages. We offer methods to support your Phase III, registration and commercial drug product manufacturing.

