

**Information sheet**

# Selecting the right formulation for your molecule

## Formulation Development

**Quotient Sciences has almost 30 years of experience developing a breadth of formulations across a range of indications. Our innovative approach to formulation development is based on our proven track record in early clinical evaluation delivering phase-appropriate formulations across the product development pathway from preclinical to late stage. Our approach has been validated by our experience with over 1,500 molecules at all stages of drug development.**

From preclinical and first-in-human (FIH) dosage forms to the optimization of your drug products for late stage development and market, 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. and a global team of over 200 formulation and analytical scientists, we offer you a formulation development service that draws on our extensive experience to identify the optimal formulation of your molecule.

### Formulation design

Quotient Sciences' formulation teams have vast experience and a proven track record 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)

#### 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
- > Amorphous (spray-dried, HME) dispersion in a bottle, capsule or tablet format

#### Gels, ointments and creams

- > Rectal
- > Topical



### 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 late stage clinical evaluation

### Pre-formulation screening

Quotient Sciences' experienced material scientists can support your pre-formulation 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.

### Early stage formulation development

Quotient Sciences' focus is on delivering the most appropriate formulations to expedite your clinical program. We support rapid progression to your first-in-human evaluation either through dosing within our Phase I clinical facilities or at an external clinical facility, 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 and, as a result, our development is based on an understanding of the final intended drug product format and the clinical program design. In addition, our experienced material science team supports the formulation development process, providing extensive characterization and data interpretation to validate lead prototype selection.

### 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 (spray drying and HME), and micronized and lipidic formulation development. Our rapid technology screening approach allows us to dramatically speed up your technology selection to improve oral bioavailability and deliver the solubilized drug molecule in your required drug product format. Our in vitro selection approach can also be supplemented by our clinical drug product optimization platform to ensure the optimal formulation is clinically validated.

### 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

We understand your analytical objectives throughout the drug development process and work with you to ensure that appropriate methodologies are available at all stages.

