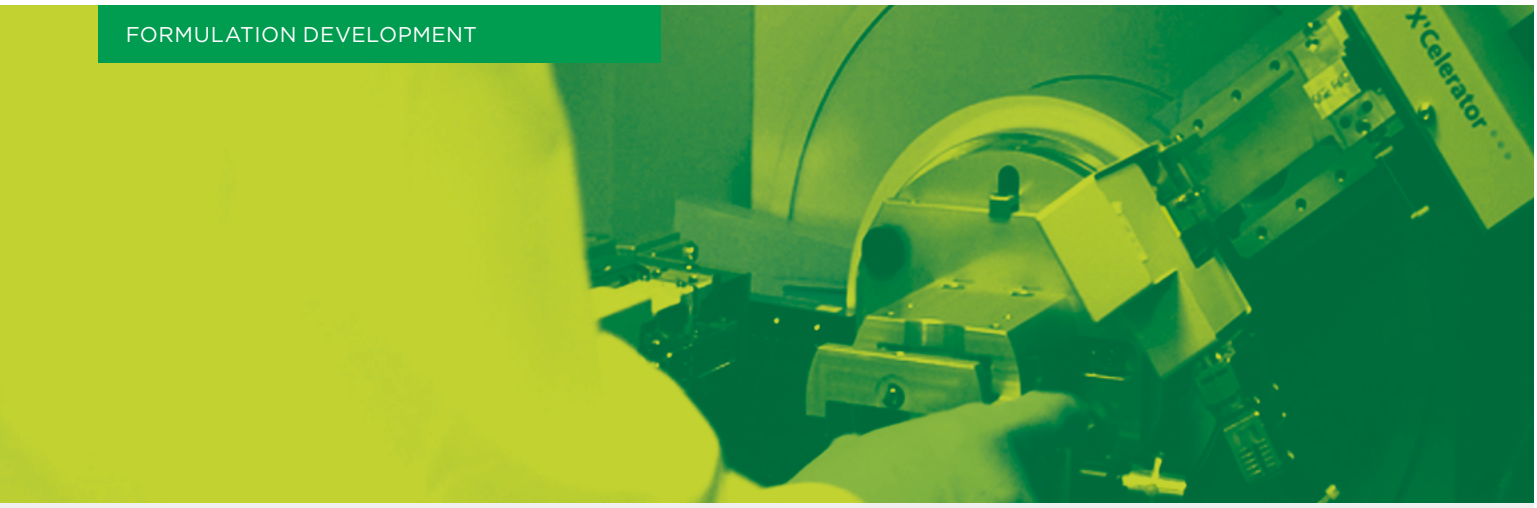
Quotient Sciences

FORMULATION DEVELOPMENT



Pre-formulation and material sciences

Providing expertise to support pre-formulation development

Our formulation development and material sciences experts have over 30 years' experience in pre-formulation and solid state characterization.

API solid form screening

We offer an early stage development service for polymorph, salt and co-crystal screening designed to rapidly understand the physico-chemical properties of your API and identify your optimal API solid form.

The assessment of LogP/LogD/pKa, pH solubility, solvent solubility and intrinsic dissolution space will help to determine the need for solubility and bioavailability enhancement to overcome potential processing challenges. Our solutions include the use of different salt forms, polymorph and amorphous forms.

No two APIs are identical, so all of our screens are individually tailored around your specific API properties and requirements.

Pre-clinical formulation development

Our experts can assist in the development of pre-clinical formulations for oral, parenteral or inhaled delivery.

For poorly soluble molecules our rapid formulation screens are developed using the Developability Classification System (DCS). Formulation technologies are evaluated based on an understanding of the molecule properties and solubility profile. Solubility enhancing techniques such as particle size reduction, lipidic systems, co-solvents, surfactants, complexation agents and amorphous dispersions can be assessed depending on the DCS class.

Biorelevant characterization dissolution techniques are used to identify lead formulation prototypes for your pre-clinical assessment. The selected pre-clinical prototypes can then be manufactured at Quotient or prepared at the Sponsor's preclinical toxicology facility.

What can Quotient's formulation development do for me?

- Identify and address critical issues quickly in early development
- Characterize your API using physical and chemical testing
- Screen formulations using bio-relevant characterization techniques
- Develop and evaluate preclinical formulation prototypes

Pre-formulation and material sciences

Bridging pre-clinical candidates to a clinical formulation

To quickly transition to a clinical formulation following pre-clinical assessment, we perform excipient compatibility screening and stability evaluations using our suite of thermal analysis instruments. With deep clinical know-how, Quotient can support the development of simple drug products for phase I trials allowing maximum dose flexibility, with the ability to rapidly transition to more robust drug products for Proof of Concept studies.

Our material sciences experts generate additional data packages to support clinical formulation development. This includes surface energetics (wettability) of API batches to ensure consistency in performance during API manufacture and scale up. Amorphous dispersion stability determination can also be used to ensure appropriate manufacturing and storage conditions are selected.

Our approaches include

- X-ray diffraction and spectroscopy for screening novel physical forms and stability prediction of amorphous systems
- Confocal Raman mapping for determining distribution of formulation components and solid form of APIs
- Vapour sorption analysis to determine the, surface area, wettability and hygroscopicity of materials
- Particle size analysis to assess the impact on molecule solubility, bioavailability and processing challenges
- Thermal analysis for rapid excipient compatibility screening
- In silico modelling using GastroPlus™ software to rapidly assess LogP/LogD/pKa

How do I characterize my API and develop a successful formulation strategy?

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