Quotient Sciences

Molecule to cure. Fast.™

Developing palatable, age-appropriate drug products

Pediatric product development

With decades of experience in developing palatable pediatric and patient-centric formulations, Quotient Sciences is actively engaged in the development of pediatric products on behalf of pharmaceutical and biotech customers.

We understand that there are a number of key factors that need to be addressed in order to successfully develop a pediatric product and achieve clinical, regulatory, and commercial success. These include the selection of age-appropriate dosage form(s), taste and palatability, choice of excipients, delivery route and administration method, and target pharmacokinetic (PK) profile.

What can Quotient Sciences do for me?

- Design and develop age-appropriate formulations focused on patient and caregiver compliance
- Characterize the taste of your drug and utilize taste-modifying/taste-masking techniques to ensure palatability
- Rapidly optimize and validate taste attributes and PK performance using adaptive clinical trials
- Apply modeling and simulation to aid dose extrapolation from adult data and predict in vivo performance of the dosage form in children
- Manufacture and supply products for dosing globally with only one to three weeks notice
- Commercial manufacture for global markets

Our expertise and capabilities in pediatric formulation development, combined with our global drug product manufacturing and clinical testing capabilities, enable us to meet the complex technical challenges of pediatric products and provide you with a unique integrated development solution. We work to customize a pharmaceutical development program for your pediatric product across its development life cycle to include preformulation studies, formulation development, analytical characterization and dosing simulation, product stability, scale-up process development, clinical trial supplies, PK/taste assessment and optimization, regulatory support, and commercial production.

Formulation Development

Our scientists have extensive experience developing palatable, age-appropriate formulations for pediatric patients and have successfully developed pediatric pharmaceutical formulations that have received regulatory approval. We will work with you to understand your requirements for all stages of development, including the Target Product Profile, and select from a full range of formulation approaches, process technologies, and taste-masking strategies with a focus on excipient selection and acceptability for the target age range.

Taste Masking

We have an extensive track record of developing age-appropriate dosage forms of aversive, bitter drug substances using a range of taste-modifying and taste-masking techniques without compromising product stability and PK performance.

What our customers are saying:

"Quotient Sciences has worked with us on several pediatric projects and been very effective in translating our product concepts into successful prototype formulations. We really appreciate the way they tune in to the broader, long-term objectives of our projects and are agile in delivering specific work packages that will contribute to the overall project's success. They are skilled in applying their extensive technical expertise and understanding of the full pediatric pharma development process. Importantly, they are great at adapting to change and tenacious when it comes to problem solving. They have proved to be an essential resource in developing our pediatric portfolio."

Proveca

Taste assessment and PK studies

Using our Translational Pharmaceutics® integrated GMP manufacturing and clinical testing platform, we perform rapid, adaptive trials in humans to assess and optimize taste attributes and PK performance to ensure clinical validation prior to proceeding to pivotal pediatric trials. Taste assessment studies can also be undertaken at an early stage, prior to pediatric formulation development, to understand the taste profile of the drug substance and the design can include alternative flavors and sweeteners or different levels of a specific flavor and sweetener[1]. We are able to modify and optimize formulation compositions in real time based on emerging clinical data.

Global patient clinical supplies

We manufacture, package, release, and supply GMP drug products ready for dosing on a worldwide basis in line with your study and recruitment needs. Our flexible options range from a personalized, per-patient basis to more traditional batch manufacturing. These customizable batch sizes conserve your API and reduce waste in the manufacturing process.

Commercial manufacture

Our production facilities in Philadelphia are fully inspected and approved by FDA, EMA, PMDA, and DEA, specializing in low-volume commercial products for orphan and niche indications.

Regulatory

We support regulatory processes and ensure that we develop age-appropriate formulations in line with your Pediatric Investigation Plans, Pediatric Study Plans, and regulatory requirements, using excipients and flavors that are globally accepted.

Formulation options	Taste-masking strategies
Solutions	Sweeteners Flavors Taste modifiers Complexation
Suspensions	
Powders and granules for reconstitution	
Orodispersible / chewable preparations	
Multiparticulates	Coatings Complexation
Minitablets	
Sprinkles	Food

For a list of our locations visit:
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Reference: [1] https://doi.org/10.1002/cpdd.1378