ThermoFisher SCIENTIFIC

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SOLVED WITH

CHEMISTRY & CONVICTION

patheon

EARLY DEVELOPMENT SOLUTIONS

Leverage an innovative partner with proven expertise in early development to ensure quick problem solving, speed and results.

Whether your company is built on a single molecule or you're a global pharmaceutical leader, you need fast, cost-effective, and scientifically based insights during early-phase development. Patheon pharma services can provide you with customized early development strategies and technical solutions leveraging our years of experience and deep technical expertise in solving complex development challenges.

A unique approach for getting solubility right the first time.

Our proprietary computational modeling program, Quadrant 2™, analyzes your compound's specific molecular structure and chemical characteristics, in combination with your unique target product profile. Using your compound's individualized data, Quadrant 2™ can predict the most promising solubility enhancement technology and excipient combination to meet your clinical and business objectives, at the earliest stages of development. This exclusive, scientifically based algorithm eliminates solubility enhancement options that are unlikely to yield benefits for your program, dramatically reducing time and investment often wasted on trial and error experimentation. What's more, the customized insights you'll get from Quadrant 2™ can help you avoid the risk of having to revise your solubility enhancement approach after Proof of Concept – a costly pitfall that can require up to 12 months of added time and incur additional costs in the range of $500,000 to $600,000.

Quadrant 2™ analyzes the molecular structure, as well as the physical and chemical characteristics of a compound based on the following information:

- API chemical structure
- Physicochemical properties
- Full-scale molecular modeling based on Quantum and Molecular Dynamic (MD) simulations
- Exclusive excipient descriptor database developed by Patheon

The Quadrant 2™ model has been confirmed via a cross-verification/model validation approach with more than 70 commercially available molecules. Validation studies have proven that the Quadrant 2™ technology selection tool is more than 90% accurate and the Quadrant 2™ excipient selection tool is more than 80% accurate. Patheon can complete computational modeling in as little as two weeks.

- Quadrant 2™ technology selection is more than 90% accurate
- Quadrant 2™ excipient selection is more than 80% accurate
- 150+ molecules analyzed using Quadrant 2™ technology and excipient selector modules

Choose the technology that's right for your molecule.

Patheon pharma services brings together multiple enabling technologies to solve more than 80% of the solubility challenges and complex formulations your molecule may encounter in early and late-phase development. These capabilities include:

- Spray drying
- Lipid formulations
- Hot-melt extrusion
- Coated beads
- Size Reduction (e.g Micronization)
- Cyclodextrin complexes

As well as formulation development, we offer extensive API and drug product manufacturing capabilities and guidance to help ensure your compound reaches the next milestone faster.

Choose the right partner to deliver high-quality Phase I materials and information needed to get you to clinic in as little as 12 weeks.

We understand your first early development goal is to get to the next milestone quickly while minimizing risk. Our Quick-to-Clinic™ program for crystalline APIs not requiring enabling technologies can deliver high-quality Phase I material in as few as 12 weeks.* This unique program includes:

- Phase appropriate analytical method development and validation
- Phase appropriate dosage forms (API in a capsule, tablet or bottle)
- Bulk packaging or simple in-house HDPE bottles
- 1-month stability testing
- Product development summary report

The result is the data you need to make informed Proof-of-Concept decisions to complete your regulatory submission. And it's good to know our reputation is unparalleled for regulatory, Right the First Time and On Time Delivery performance.

*Quadrant 2™ is not required to proceed to Quick to Clinic™ and 12 week timeline does not include solubility work.

We are committed to getting you to clinic, and are capable of getting you to commercial.

When your compound is ready to advance to late-phase clinical trials and commercialization, our team is here for you. Our fully integrated and automated process ensures that your technology will be transferred quickly and successfully.

- 100+ dosage forms
- 74% of our clients are new and emerging companies

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