Proveris by Design™ for Generic Oral Products

TEST SERVICES

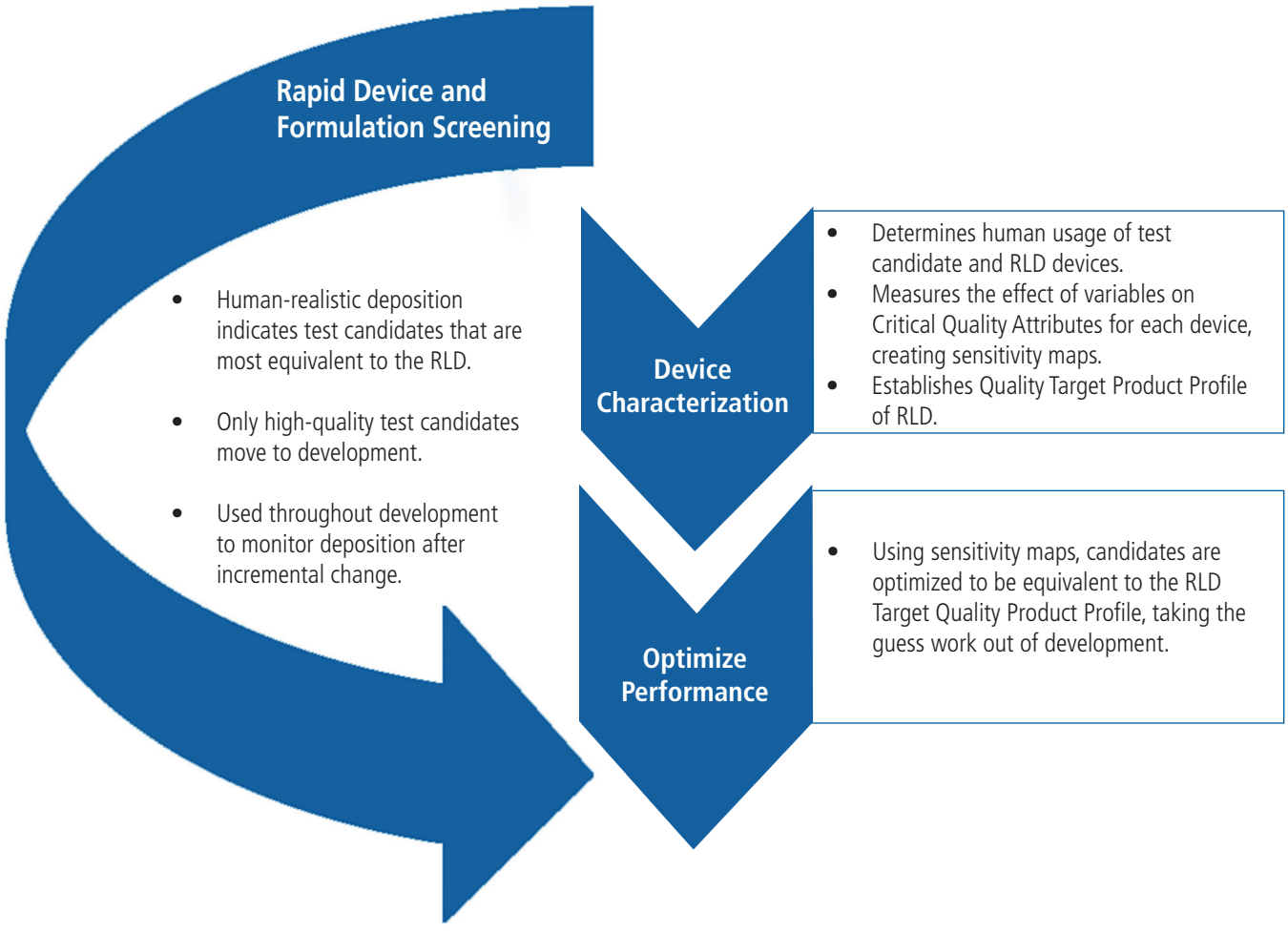
A proven process for rapid product development and risk-reduced submissions

proveris®
LABORATORIES

Inhalation drugs are the most challenging drug products to develop. Generic applications due to their complexity can have failure rate of up to 90%. Understanding the intricate relationship between the formulation, device, and human actuation is essential to reducing risk of these complex combination drug products. To succeed and reduce time to market, you need a partner who can manage these complexities with a proven, systematic process that reduces time and cost while ensuring high quality. The Proveris by Design process has been proven for over 25 years to provide the shortest, most effective path to submission by delivering rapid, unbiased insights into device and formulation performance.

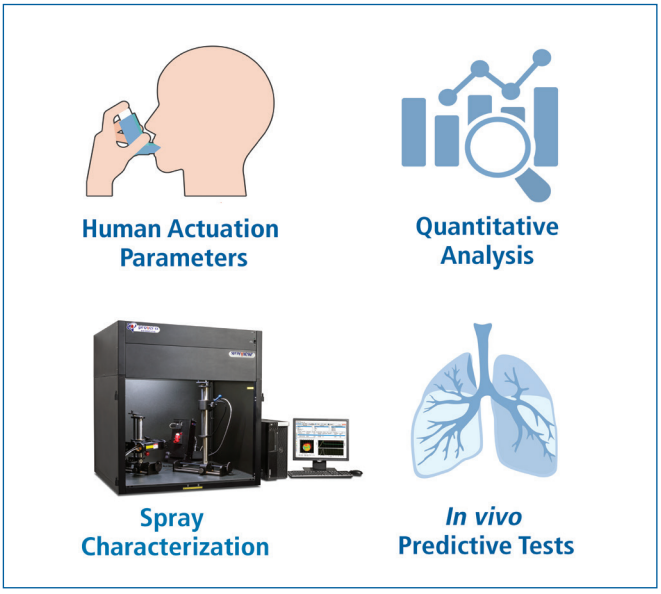
Success Starts with a Successful Process

Proveris by Design assesses the complex variables inherent in combination drug products to identify critical parameters that impact product performance and optimizes them for successful product approvals. Based on the fundamentals of Quality by Design, Proveris by Design has been shown to minimize late-stage failures, shorten development times, simplify submissions, and reduce cost.



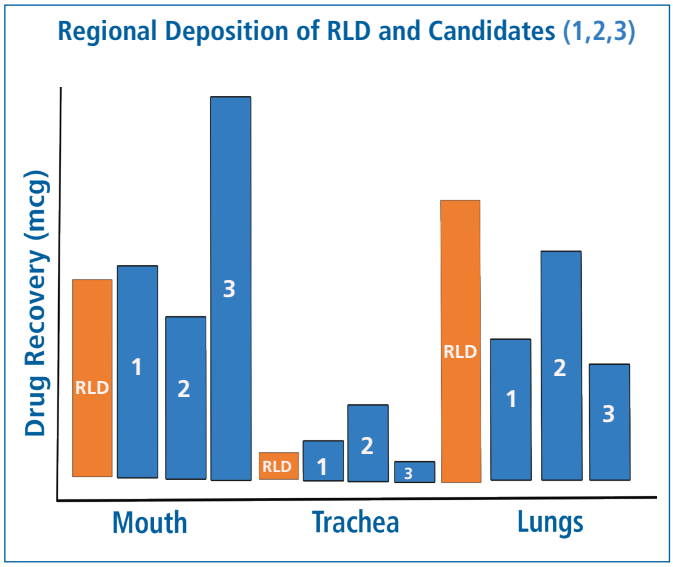
Understand Your Devices

Developing a product to be equivalent to the reference labeled drug requires a complete understanding of your candidates and the reference product's attributes and performance as it is used by the intended demographic. Proveris by Design uses proprietary technologies that measure specific human actuation characteristics which drive product performance. Comprehensive characterization of product outputs is then used to define the Quality Target Product Profile. The sensitivity maps produced during this process determine the appropriate design space for product development and provide the framework to ensure equivalency to the RLD.



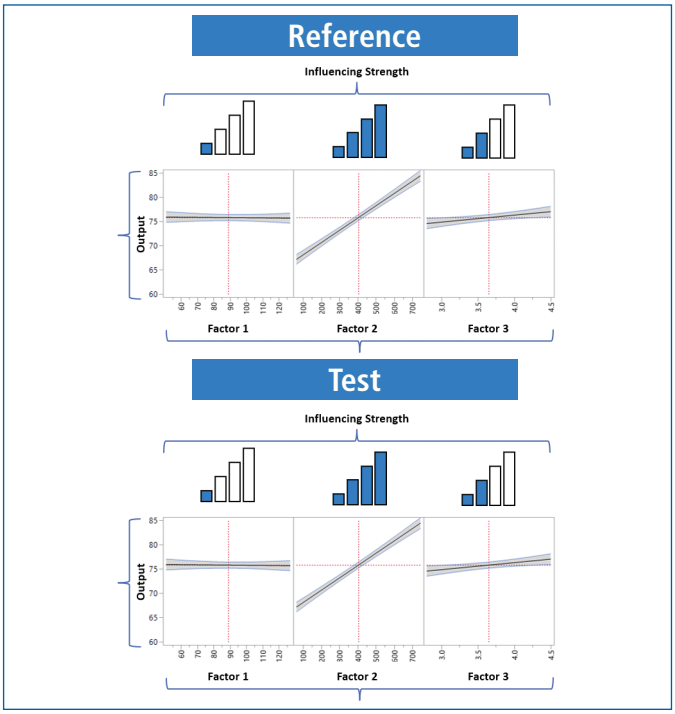
Rapid Screening Reduces Risk

Successful generic inhaled drug approval depends on equivalent deposition of drug in the lungs. Comparative screening of multiple drug device combinations to observe quantitative regional deposition, under human-realistic conditions, is the best early indicator of equivalence. Proveris Labs can screen up to 20 device and formulation candidates in a single day and provide quantitative results on regional deposition, allowing you to quickly eliminate candidates that do not show equivalent deposition. This process significantly reduces risk, time, and cost by only advancing candidates that show equivalence.



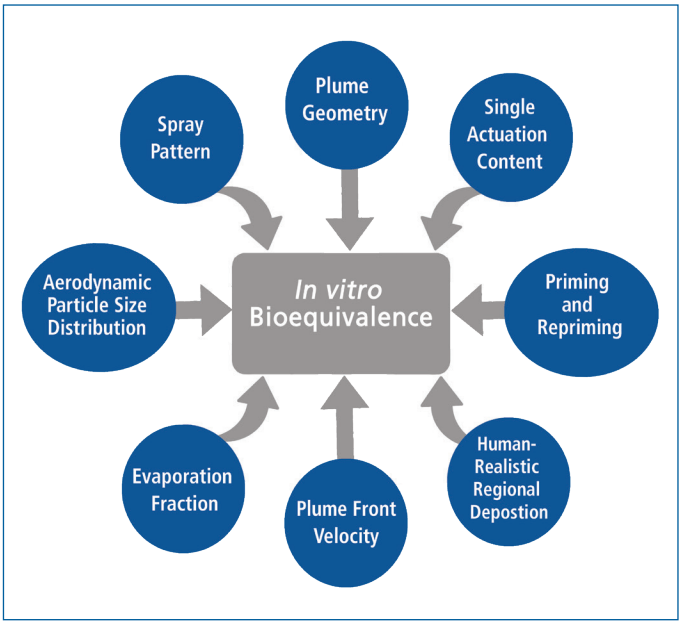
Performance Optimized

Adjustments to formulations and devices can be time-consuming and may not yield the desired performance result. The characterization of the target product combined with the sensitivity maps generated by the Proveris by Design process provides the model of each parameter's influence on performance characteristics. This takes the guess work out of development and allows you to confidently tailor device performance for an equivalent generic product.



Feel the Weight of Evidence

The FDA refers to weight of evidence as a systematic approach in which investigators look at all relevant evidence to make an assessment or determination. The Proveris by Design weight of evidence approach expands the toolbox for bioequivalence testing, employing all relevant tests, including new technologies, to build the most comprehensive demonstration of equivalence from start to finish. Extensive data generated during projects with Proveris Laboratories builds an overwhelming weight of *in vitro* evidence, helping you develop the most equivalent candidate for clinical endpoint studies, greatly reducing risk of late-stage failures.



Robust Methods, Transfer, and QC Support

Approvals are just the first step in the commercialization process. Proveris has the expertise to help you throughout commercialization, providing method transfer and validation, training, instrumentation, and access to comprehensive data generated during the project. In addition, the Proveris by Design process provides a complete characterization of the new product that can be invaluable in addressing out of specification results and product sustaining issues into the future.

A Trusted Partner for Over 25 Years

Proveris Laboratories has been a proven partner with innovator and generic companies around the world for over 25 years. We work with you to find the most appropriate and efficient path for your product to reach the market. The industry leader in spray characterization, instrumentation, and service, combined with driving new innovative technologies to support recent regulatory advancements to reduce clinical endpoint studies, Proveris is the right choice for your OINDP development needs.

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