Proveris Laboratories as a Research Partner

The balance of the timelines for developing new products versus evaluating all options always weighs on research scientists. Partnering with Proveris allows initial evaluation of a wider variety of devices and formulations that is normally achievable using only internal resources.

Proveris scientists have focused for over twenty years on helping their customers evaluate and deliver quality orally inhaled and nasal drug products (OINDPs). Our vast experience allows options to be discussed and protocols refined in shorter times and reduced budgets.

The Proveris laboratory approach accelerates research timelines and provides more efficient technology transfer.

Proveris offers full characterization, including spray pattern, plume geometry, shot weight, droplet size distribution, dose content, aerodynamic particle size distribution, product actuation force, spray duration and spray velocity.

Device-Formulation Screening
Proveris will work with you to evaluate the spray performance on the device candidates. With this process you can select the best device-formulation combination by evaluating all key characteristics. Formulation changes can be measured and evaluated on multiple actuators. The Proveris model then thoroughly evaluates and documents the effect of each change, providing the most comprehensive study and complete documentation available.

Qualitative Spray Characterization
Faster timelines and lower costs can be achieved through qualitative evaluations. Initial screening of devices can be expedited by using a qualitative evaluation of multiple devices. The program can be used for early stage device evaluation, reference and generic comparison and pre-clinical characterization.

Sensitivity Mapping
Optimizing device parameters requires a thorough understanding of not only the device characteristics but also the "strength of influence" each input parameter has on the total performance. The Proveris Quality by Design (QbD) and Design of Experiments (DOE) principles determine the rank-ordered influence that a set of inputs has on an output. This process systematically determines the strongest influencing factors on an output, allowing for rapid knowledge generation and focused prioritization for later experiments.

Pre-Clinical Evaluation
In vitro equivalence does not guarantee *in vivo* bioequivalence. Taking *in vitro* testing to the next level of understanding provides the best chance of *in vivo* success.

Accelerate Development with Proveris Laboratories

Achieve the following with Proveris in less than two months with Proveris Laboratories

- Device-formulation Selection
- Robust Method Development based on FDA recommended Quality by Design (QbD) approach
- Product understanding based on sound science
- Identify input variabilities influencing critical quality attributes (CQAs)

Proveris Laboratories as a Research Partner

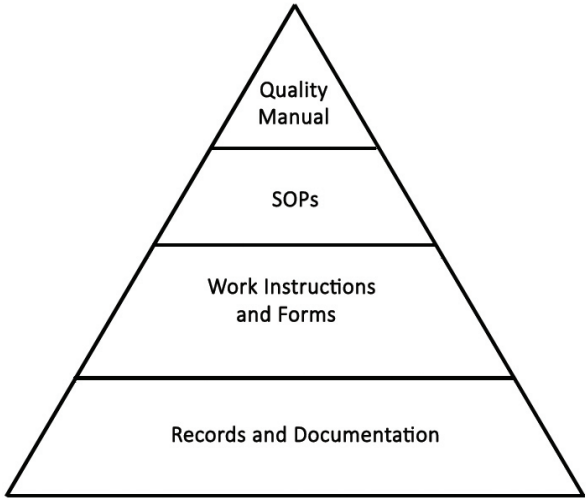
Proveris's laboratory staff follows the highest quality standards in developing protocols and implementing procedures. Our projects deliver services and documentation that are thorough, robust and easily transferred.

Our quality programs are designed to document every aspect of key quality parameters including methods, equipment parameters, report design, and data review.

Proveris is certified to ISO 9001:2015

We understand global regulatory guidelines and our Quality by Design process offer documented evidence of protocols that meet the appropriate local and global requirements. This includes areas such as 21 CFR Part 11 compliance with complete audit trails of operator activities, instruments settings, calibration, and data measurement.

Partnering with Proveris allows scientists to focus on the research and not creating technology transfer documents.



Proveris incorporates core quality assurance functions in its business practices.

Integrated Suite of Equipment for Nasal and pMDI Devices

Equipment evaluation is based on optimally testing each parameter including system performance, training of operators, evaluation of method and SOP robustness, understanding the benefits of upgrades, and planning the optimum times for implementation.

pMDI Devices

Nasal Sprays

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